Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market

Final report

Gesundheit Österreich GmbH, S&P Global, Areté, Civic Consulting

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The study team also sincerely thanks the experts who were available for **exploratory and/or follow-up interviews**. Organisations and experts (that gave their consent) are listed in alphabetical order by institution below.

Institution	Interview partner (if consent given to be named)
Agency for Medicinal Products and Medical Devices (HALMED), Croatia	Krunoslav Kranjec
Austrian Agency for Health and Food Safety GmbH (AGES), Austria	Andreas Amon
Association of Medical Device Reprocessors (AMDR), main office: USA; European office: Germany	Daniel Vukelich
Bravis Hospital, the Netherlands	-
Centre for Sustainable Hospitals (CfSH), Denmark	Maria Gaden
Danish Medicines Agency (DKMA), Denmark	-
Directorates-General of the French Ministry of Health (DGS), France	-
Federal Agency for Medicines and Health Products (AFMPS), Belgium	-
Federal Institute for Drugs and Medical Devices (BfArM), Germany	-
Federal Ministry of Health, Germany	-
Finnish Medicines Agency (FIMEA), Medical Devices Unit, Finland	-
French National Agency for Medicines and Health Products Safety (ANSM), France	-
Health Products Regulatory Authority (HPRA), Ireland	-
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Federal Ministry of Social Affairs, Health, Care and Consumer Protection, Austria	Martin Renhardt
-	Dario Pirovano
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NB0318 – Centro Nacional de Certificacion de Productos Sanitarios, Spain	Julia Caro Barri
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NB1434 – Polskie Centrum Badan i Certyfikacji S.A, Poland	Tomasz Koeber
NB2460 – DNV Product Assurance AS, Norway	-
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Abstract (in English, French and German)

English

Article 17 of Regulation (EU) 2017/745 (Medical Device Regulation – MDR) regulates the reprocessing of single-use devices (SUDs) with relevance for the European Economic Area (EEA) which may only take place where permitted by national law and in accordance with this article. This study evaluates how the provisions established in Article 17 MDR have been implemented and how such provisions function in practice. For this purpose, the current market situation for the reprocessing and reuse of SUDs was surveyed and analysed across 30 European countries (EU-27 plus Iceland, Liechtenstein and Norway). This report presents an overview of national decisions regarding the reprocessing of SUDs in the countries studied (ranging from permitted to prohibited to no decision taken at all). The study also reports on the certification processes for SUDs by notified bodies, the reprocessing of SUDs by manufacturers and health institutions and the reuse of purchased reprocessed SUDs by health institutions. Perceived challenges and opportunities as well as actions recommended by stakeholders are included as well. The report closes with a series of conclusions and recommendations for optimising the implementation of Article 17 MDR in Europe.

French

L'article 17 du règlement (UE) 2017/745 (règlement relatif aux dispositifs médicaux – MDR) régit le retraitement des dispositifs à usage unique (Single-use devices, SUDs) présentant un intérêt pour l'Espace économique européen, qui ne peut être effectué que si la législation nationale l'autorise et est conforme à cet article. Cette étude évalue la manière dont ces dispositions ont été mises en œuvre et comment ces dispositions fonctionnent dans la pratique. À cet effet, la situation actuelle du marché du retraitement et de la réutilisation des SUD a été étudiée et analysée dans les 30 pays européens (UE-27, Islande, Liechtenstein et Norvège). Ce rapport présente une vue d'ensemble des décisions nationales concernant le retraitement des SUD dans les pays étudiés (allant de l'autorisation à l'interdiction, en passant par l'absence de décision). L'étude rend également compte des processus de certification des SUD par les organismes notifiés (notified bodies), du retraitement des SUD par les fabricants et les établissements de santé, ainsi que de la réutilisation des SUD retraités par les établissements de santé. Les défis et les opportunités perçus, ainsi que les actions recommandées par les parties prenantes sont également inclus dans le rapport, qui se termine par une série de conclusions et de recommandations visant à optimiser la mise en œuvre de l'article 17 MDR en Europe.

German

Artikel 17 der Verordnung (EU) 2017/745 über Medizinprodukte (Medical Device Regulation – MDR) regelt die Aufbereitung und Weiterverwendung von Einwegprodukten (Single-use devices, SUDs) im Europäischen Wirtschaftsraum, die nur dann erfolgen darf, wenn dies nach nationalem Recht und in Übereinstimmung mit diesem Artikel zulässig ist. In der vorliegenden Studie wurde untersucht, wie die in Artikel 17 MDR festgelegten Bestimmungen umgesetzt wurden und wie sie in der Praxis funktionieren. Zu diesem Zweck wurde die aktuelle Marktsituation für die Aufbereitung und Wiederverwendung von SUDs in 30 europäischen Ländern (EU-27 plus Island, Liechtenstein und Norwegen) erhoben und analysiert. Der Bericht bietet eine Übersicht, welche Entscheidungen in puncto Wiederaufbereitung von SUDs die untersuchten Länder getroffen haben (in den Kategorien von erlaubt über verboten bis hin zu keiner Entscheidung). Die Studie berichtet auch über die Zertifizierungsprozesse für SUDs durch Benannte Stellen (notified bodies), die Wiederaufbereitung durch die Hersteller von SUDs und Gesundheitseinrichtungen sowie die Wiederverwendung von gekauften wiederaufbereiteten SUDs durch Gesundheitseinrichtungen. Auch die von den Interessengruppen angeführten Herausforderungen und Chancen sowie die empfohlenen Maßnahmen werden dargestellt. Der Bericht schließt mit einer Reihe von Schlussfolgerungen und Empfehlungen zur Optimierung der Umsetzung des Artikels 17 MDR in Europa.

Executive summary

Background

Article 17 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation – MDR) on medical devices (MDs) introduced new legal requirements for reprocessing single-use devices (SUDs) which **may only take place where permitted by national law and in accordance with this Article** and **two reprocessing options**: (1) any natural or legal person who reprocesses a SUD must be considered to be the **manufacturer** (MF) of the reprocessed device and must assume the obligations incumbent on MFs; (2) any health institution (HI) that reprocesses and uses a SUD in-house must comply with **common specifications** (CS). To evaluate how the provisions established in Article 17 MDR have been implemented by the 27 EU Member States, Iceland, Liechtenstein and Norway and how such provisions operate, DG SANTE (via HaDEA)[1] contracted a **Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market** to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with S&P Global, Areté and Civic Consulting. The study took place between 15 December 2022 and 14 February 2024 (14 months). **Three main study questions were addressed**: (1) what is the current situation in the EU for reprocessing of SUDs?; (2) which obstacles and challenges might affect the reprocessing of SUDs in the EU?; (3) which possible solutions and recommendations could be used to address potentially identified issues?

Methods

The study used a **mixed-method approach** including data and information collection via a **literature review** and **stakeholder involvement** in the form of **targeted surveys** and **interviews** (exploratory and follow-up interviews). The study team incorporated **triangulation** at various points in the research process by applying different methods and by accessing different sources of information. **Four main stakeholder groups** were identified as being relevant for the study's objective: (1) competent authorities on MDs, (2) notified bodies (NBs) designated under the MDR, (3) manufacturers (MFs) that reprocess SUDs, (4) health institutions (HIs) reprocessing and reusing SUDs. Online surveys targeting each of the four stakeholder groups took place between May and September 2023. In total, **32 follow-up interviews** were led from May to October 2023 through online meeting platforms. As the data collected in this study were intended to reflect the situation up to the end of 2023, a survey update was carried out with all stakeholders apart from HIs (no changes expected) between November and

[1] Specific contract No 2021 P3 04, implementing framework contract No SANTE/2021/OP/0002.

December 2023 to inquire about any (actual or planned) changes compared to the initial survey.

Results

Regulatory implementation of Article 17 MDR: among the 30 surveyed countries, 17 have prohibited the reprocessing of SUDs (Austria, Bulgaria, Cyprus, the Czech Republic, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Liechtenstein, Lithuania, Malta, Norway, Romania, Slovakia). In contrast, 10 countries (Belgium, Croatia, Denmark, Germany, Iceland, Ireland, the Netherlands, Poland, Spain, Sweden) allow reprocessing. The remaining three countries (Luxembourg, Portugal, Slovenia) have yet to take a decision. National provisions such as laws or guidelines regulating the reprocessing and further use of SUDs in accordance with Article 17(1) MDR exist in 8 of the 17 countries where reprocessing is prohibited and in 9 of the 10 countries that allow it.

Practical implementation of Article 17 MDR: only 6 of the 42 surveyed NBs designated under the MDR indicated that they certify reprocessed SUDs or the reprocessing of SUDs. Reasons given for the majority of NBs not engaging in certification include a lack of designation for this activity, the prohibition of reprocessing SUDs in the country and low client interest. Applications for the certification of SUDs are limited, with only two NBs having received applications and no certificates issued so far for compliance with the CS. Moreover, MFs and CAs reported challenges regarding the identification of NBs for the certification of reprocessed SUDs. Furthermore, only two identified MFs (both based in Germany) actually reprocess SUDs for the EU market. Around half (9 out of 19) of the HIs currently reprocess SUDs, or plan to do so, in countries where reprocessing is allowed. Reasons for not reprocessing or reusing reprocessed SUDs given by some HIs include the perception of limited benefits, a lack of experience in reprocessing, an inability to obtain certification for compliance with the CS and safety concerns.

Challenges and opportunities: consultation activities with the four stakeholder groups revealed a number of perceived challenges and opportunities. All stakeholders stated that potential health risks for patients from reprocessed SUDs creates uncertainty, with varying perceptions of the evidence. In particular, it is a challenge to correctly record any incident related to reprocessed SUDs in national surveillance systems. The suitability of some devices for reprocessing is also contentious among stakeholders; there are ethical and legal concerns as well as doubts about reprocessing as a concept per se. Conversely, stakeholders consider cost savings and environmental advantages as opportunities of reprocessing SUDs.

Stakeholder-recommended actions and ongoing discussions: potential actions suggested by the stakeholders to encourage the reprocessing of SUDs include the strengthening of regulatory requirements (to gain clarity and a common understanding); the implementation of a clear tracking system (to

reduce risks); and enhanced training and risk management. There is consensus among the stakeholders regarding the need for additional evidence obtained from scientific studies and discussions in expert groups. Policy debate about potentially permitting the reprocessing of SUDs is taking place in multiple countries, with evidence generation in the form of scientific studies and legal changes being considered.

Conclusions

The survey on how the provisions established in Article 17 MDR have been implemented by the countries involved shows a **very diverse picture**: only 10 countries allow the reprocessing of SUDs. However, as there are very few studies on the subject, there is a need to obtain further evidence, and this could also support decisions on allowing or prohibiting the reprocessing of SUDs. The **fragmentation and complexity in implementation** due to various national regulations leads to a potential knowledge gap in MFs and HIs regarding the legal context of reprocessing in different countries. Furthermore, since only a **few NBs certify reprocessed SUDs or reprocessing SUDs** and no MDR certificates have been issued so far, limited access to certification was identified as a bottleneck.

Recommendations

A set of **17 recommendations** was developed to remove obstacles in the implementation of Article 17 MDR and clustered in **five topics** by the study team based on the evidence collected in the course of the study, including the insights from the four key stakeholder groups in the surveys and interviews. **General recommendations** include the promotion of further evidence generation through targeted research programmes initiated by CAs or even at EU level or to increase clarity and transparency on the national implementation of Article 17 MDR. Regarding the **legal EU framework documents**, it is recommended to produce guidance documents (e.g. Q&As) for key targeted stakeholders, which ideally contain a step-by-step manual for the implementation of Article 17 MDR and the CS in particular. To remove obstacles in the **certification process** it is recommended to inform about which NBs are designated for certifying the reprocessing of SUDs and to clarifiy certification for compliance with the CS. It is key that **Member States take targeted measures** in different areas to support and complement EC action, such as information campaigns or capacity building measures for HIs. **Product-related recommendations** include the drafting of guidance documents on the suitability of different types of SUDs for reprocessing.

Keywords

Regulation (EU) 2017/745 on medical devices, Article 17 MDR, single-use devices, reprocessing, reusing

Resumé

Contexte

L'article 17 du règlement relatif aux dispositifs médicaux (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 (Medical Device Regulation, MDR) a introduit de nouvelles exigences légales pour le retraitement des dispositifs à usage unique (Single-use devices, SUDs) **qui ne peut avoir lieu que lorsque le droit national l'autorise et conformément à cet article en appliquant deux options de retraitement**: (1) Toute personne physique ou morale qui retraite un SUD doit être considérée comme le fabricant du dispositif retraité et doit assumer les obligations qui incombent aux fabricants. (2) Toute institution de santé qui retraite et utilise un SUD en interne doit se conformer aux spécifications communes (common specifications, CS). Afin d'évaluer comment les dispositions établies à l'article 17 MDR sur les SUDs et leur retraitement ont été mises en œuvre par les 27 États membres de l'Union Européenne (UE), l'Islande, le Liechtenstein et la Norvège et comment ces dispositions fonctionnent, une **Étude sur la mise en œuvre de l'article 17 du règlement (UE) 2017/745 relatif aux dispositifs médicaux sur le marché de l'UE** a été confiée à un consortium dirigé par l'Institut national autrichien de santé publique (Gesundheit Österreich GmbH / GÖG), en collaboration avec S&P Global, Areté et Civic Consulting par la DG SANTE (via HaDEA). L'étude a été réalisée du 15 décembre 2022 au 14 février 2024 (pendant 14 mois). **Trois questions principales ont été abordées dans le cadre de l'étude**: (1) Quelle est la situation actuelle dans l'UE pour le retraitement des SUDs? (2) Quels sont les obstacles et les défis qui pourraient affecter le retraitement des SUDs dans l'UE? (3) Quelles sont les solutions et les recommandations possibles pour le retraitement des SUDs?

Méthodes utilisées

L'étude a utilisé une **approche mixte**, comprenant la collecte de données et d'informations par le biais d'une analyse documentaire et l'implication des parties prenantes sous la forme d'enquêtes et d'entretiens ciblés (entretiens exploratoires et de suivi). L'équipe chargée de l'étude a intégré la **triangulation** à divers moments du processus de recherche en appliquant différentes méthodes et en accédant à différentes sources d'information. **Quatre principaux groupes de parties prenantes ont été identifiés** comme pertinents pour l'objectif de l'étude incluant (1) les autorités compétentes en matière de dispositifs médicaux, (2) les organismes notifiés (NB) désignés dans le cadre de MDR, (3) les fabricants qui retraitent les SUDs et (4) les établissements de santé qui retraitent et réutilisent les SUDs. Un ensemble de **sept questionnaires dans quatre enquêtes en ligne**, ciblant chacun des quatre groupes de parties prenantes, a été conduite entre mi-mai et septembre 2023. Au total, 32 entretiens de suivi ont été menés de mai à octobre 2023 par réunion en ligne. Compte tenu que la collecte de données dans le cadre de cette étude devait refléter la situation

jusqu'à la fin de l'année 2023, une **enquête actualisée a été lancée** auprès de toutes les parties prenantes, à l'exception des établissements de santé (pour lesquels aucun changement n'était prévu), entre novembre et décembre 2023, afin de s'enquérir de tout changement (réel ou prévu) par rapport à l'enquête initiale.

Résultats de l'enquête

Mise en œuvre réglementaire de l'article 17 MDR: parmi les 30 pays étudiés, 17 ont interdit le retraitement des SUDs (Autriche, Bulgarie, Chypre, République tchèque, Estonie, Finlande, France, Grèce, Hongrie, Italie, Lettonie, Liechtenstein, Lituanie, Malte, Norvège, Roumanie, Slovaquie). En revanche, dix pays (Belgique, Croatie, Danemark, Allemagne, Islande, Irlande, Pays-Bas, Pologne, Espagne, Suède) autorisent le retraitement. Les trois pays restants (Luxembourg, Portugal, Slovénie) n'ont pas encore pris de décision. Des dispositions nationales réglementant le retraitement et l'utilisation ultérieure des SUDs conformément à l'article 17(1) MDR existent dans neuf des dix pays qui l'autorisent, et dans huit des 17 pays où le retraitement est interdit.

Mise en œuvre pratique de l'article 17 MDR: En ce qui concerne la mise en œuvre pratique de l'article 17, seuls six des dix organismes notifiés interrogés ont indiqué qu'ils certifiaient les SUDs retraités. Les raisons pour lesquelles la majorité des organismes notifiés ne s'engagent pas dans la certification sont le manque de désignation, l'interdiction des SUDs retraités dans le pays et le faible intérêt des clients. Les demandes de certification des SUD sont limitées jusqu'à présent, seuls deux organismes notifiés ayant reçu des demandes, et aucun certificat n'ayant été délivré jusqu'à présent concernant la conformité avec les CS. En outre, les fabricants et les autorités compétentes ont signalé des difficultés concernant l'identification des organismes notifiés pour la certification des SUDs retraités. Au moment de l'étude, aucun organisme notifié n'est qualifié pour certifier le retraitement conformément à l'article 17(4) MDR (CS). Près de la moitié (neuf des 19) établissements de santé interrogés retraitent actuellement les SUDs ou prévoient de le faire dans les pays où le retraitement est autorisé. Les raisons invoquées par certains établissements de santé pour ne pas retraiter/réutiliser les SUDs retraités sont la perception d'avantages limités, le manque d'expérience en matière de retraitement et l'impossibilité d'obtenir une certification de conformité avec les CS et les problèmes de sécurité.

Défis et opportunités: Les activités de consultation avec les quatre groupes de parties prenantes ont révélé un certain nombre de défis et d'avantages perçus. Tous les intervenants ont indiqué que les risques potentiels pour la santé des patients liés aux SUDs retraités créent de l'incertitude, avec des perceptions variées sur les preuves. En particulier, il est également difficile d'enregistrer correctement tout incident lié aux SUDs retraités dans les systèmes de surveillance nationaux. L'aptitude de certains dispositifs à être retraités est controversée parmi les parties prenantes; Il y a des préoccupations éthiques et juridiques, ainsi que des doutes sur le retraitement en tant que concept en soi. À

l'inverse, les parties prenantes considèrent que le retraitement des SUDs permet de réaliser des économies et de préserver l'environnement.

Actions recommandées par les parties prenantes et discussions en cours: Les mesures potentielles suggérées par les intervenants pour encourager davantage le retraitement des SUDs comprennent le renforcement des exigences réglementaires (pour obtenir une clarté et une compréhension commune), la mise en œuvre d'un système de suivi clair (pour réduire les risques) et l'amélioration de la formation et de la gestion des risques. Les parties prenantes s'accordent sur la nécessité de produire des preuves supplémentaires par le biais d'études scientifiques et de discussions au sein de groupes d'experts. Un débat politique sur la possibilité d'autoriser le retraitement des SUDs a lieu dans de nombreux pays, avec la production de preuves sous la forme d'études scientifiques et de changements juridiques envisagés.

Conclusions

L'enquête sur la façon dont les dispositions de l'article 17 MDR ont été mises en œuvre par les pays étudiés montre **une image très diverse**: Seuls 10 pays autorisent le retraitement des SUDs. Cependant, comme il y a très peu d'études sur le sujet, il est nécessaire d'obtenir des preuves supplémentaires, qui pourraient également soutenir les décisions d'autoriser ou d'interdire le retraitement des SUDs. La fragmentation et la complexité de la mise en œuvre dues aux diverses réglementations nationales entraînent un manque potentiel de connaissances chez les fabricants et les établissements de santé en ce qui concerne le contexte juridique du retraitement dans les différents pays. En outre, étant donné que seuls quelques organismes notifiés certifient les SUDs retraités ou les retraitent les SUDs, et qu'aucun certificat MDR n'a été délivré jusqu'à présent, l'accès limité à la certification a été identifié comme un goulot d'étranglement.

Recommandations

L'équipe chargée de l'étude a élaboré et regroupé un ensemble de **17 recommandations dans cinq domaines** afin de lever les obstacles à la mise en œuvre de l'article 17 MDR, sur la base des éléments recueillis au cours de l'étude, y compris les informations fournies par les quatre principales parties prenantes lors des enquêtes et des entretiens. Les recommandations générales comprennent la promotion de la production de preuves supplémentaires par le biais de programmes de recherche ciblés lancés par les autorités compétentes ou même au niveau de l'UE, ou pour accroître la clarté et la transparence de la mise en œuvre nationale de l'article 17 MDR. En ce qui concerne les documents-cadres juridiques de l'UE, il est recommandé de produire des documents d'orientation (par exemple, des questions-réponses) pour les principales parties prenantes ciblées, qui contiennent idéalement un manuel étape par étape pour la mise en œuvre de l'article 17 MDR et des CS en particulier. Afin d'éliminer les obstacles au processus de certification, il est recommandé d'informer sur les NB

désignés pour certifier les SUDs de retraitement et de clarifier la certification pour la conformité avec les CS. Il est essentiel que les États membres prennent des mesures ciblées dans différents domaines pour soutenir et compléter l'action de la Commission européenne, telles que des campagnes d'information ou des mesures de renforcement des capacités pour les établissements de santé. Les recommandations relatives aux produits comprennent la rédaction de documents d'orientation sur l'adéquation des différents types de SUDs au retraitement.

Mots-clés

Règlement (UE) 2017/745 relatif aux dispositifs médicaux, MDR, article 17, dispositifs à usage unique, retraitement, réutilisation.

Kurzfassung

Hintergrund

Mit Artikel 17 der Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 5. April 2017 (Medical Device Regulation – MDR) über Medizinprodukte (MD) wurden neue rechtliche Anforderungen für die Aufbereitung und Weiterverwendung von Einwegprodukten (Single-use devices – SUDs) eingeführt, die nur erfolgen darf, wenn dies **nach nationalem Recht zulässig ist und im Einklang mit diesem Artikel** und **zwei verschiedenen Aufbereitungsoptionen** steht: (1) Jede natürliche oder juristische Person, die ein Einwegprodukt aufbereitet, gilt als **Hersteller** (MF) des aufbereiteten Produkts und übernimmt die Pflichten, die MFs obliegen. (2) Für aufbereitete Einwegprodukte, die in einer Gesundheitseinrichtung (HI) verwendet werden, müssen die **gemeinsamen Spezifikationen** (CS) eingehalten werden. Um zu bewerten, wie die in Artikel 17 MDR festgelegten Bestimmungen von den 27 EU-Mitgliedstaaten sowie von Island, Liechtenstein und Norwegen umgesetzt wurden und wie diese Bestimmungen funktionieren, wurde von der GD SANTE (über HaDEA) eine **Studie über die Umsetzung von Artikel 17 der Verordnung (EU) 2017/745 über Medizinprodukte auf dem EU-Markt** an ein Konsortium unter Leitung des österreichischen nationalen Public-Health-Instituts Gesundheit Österreich GmbH (GÖG) in Zusammenarbeit mit S&P Global, Areté und Civic Consulting vergeben. Die Studie wurde im Zeitraum vom 15. Dezember 2022 bis zum 14. Februar 2024 (Laufzeit: 14 Monate) durchgeführt. **Es wurden drei Hauptfragen definiert:** (1) Wie sieht die aktuelle Situation in der EU in puncto Wiederaufbereitung von SUDs aus? (2) Welche Hindernisse und Herausforderungen könnten die Wiederaufbereitung von SUDs in der EU beeinträchtigen? (3) Welche möglichen Lösungen und Empfehlungen könnten genutzt werden, um die potenziell identifizierten Probleme zu lösen?

Methoden

In der Studie wurde ein **Mixed-Methods-Ansatz** angewandt, der eine **Literaturrecherche** zur Sammlung von Daten und Informationen und die **Einbeziehung von Interessengruppen** in Form von **gezielten Umfragen** und **Interviews** (Sondierungs- und Follow-up-Interviews) umfasste. Das Studienteam nahm an verschiedenen Stellen im Forschungsprozess eine **Triangulation** vor, indem es unterschiedliche Methoden anwandte und auf unterschiedliche Informationsquellen zurückgriff. **Es wurden vier Hauptinteressengruppen** ermittelt, die für das Ziel der Studie relevant sind: (1) für Medizinprodukte zuständige Behörden, (2) gemäß der MDR Benannte Stellen, (3) Hersteller, die SUDs aufbereiten, (4) Gesundheitseinrichtungen, die SUDs aufbereiten und weiterverwenden. Zwischen Mai und September 2023 wurden Onlineumfragen durchgeführt, die sich an alle vier Interessengruppen richteten. Darüber hinaus wurden von Mai bis Oktober 2023 insgesamt **32 Folgegespräche** via Onlineplattformen geführt. Da die Datenerhebung in dieser Studie die Situation

bis Ende 2023 widerspiegeln sollte, wurde im November und Dezember 2023 eine aktualisierte Umfrage mit allen Interessengruppen – mit Ausnahme der HIs, bei denen keine Änderungen zu erwarten waren – durchgeführt, um etwaige (tatsächliche oder geplante) Änderungen im Vergleich zur ersten Umfrage zu erfragen.

Ergebnisse

Gesetzliche Umsetzung von Artikel 17 MDR: Von den 30 befragten Ländern haben 17 die Wiederaufbereitung von SUDs verboten (Bulgarien, Estland, Finnland, Frankreich, Griechenland, Italien, Lettland, Liechtenstein, Litauen, Malta, Norwegen, Österreich, Rumänien, Slowakei Tschechien Ungarn, Zypern). Im Gegensatz dazu erlauben zehn Länder (Belgien, Dänemark, Deutschland, Irland, Island, Kroatien, die Niederlande, Polen, Schweden, Spanien) die Wiederaufbereitung. Die übrigen drei Länder (Luxemburg, Portugal, Slowenien) haben noch keine Entscheidung getroffen. Nationale Bestimmungen, wie Gesetze oder Leitlinien zur Regelung der Aufbereitung und Weiterverwendung von SUDs gemäß Artikel 17(1) MDR, gibt es in neun der zehn Länder, die dies erlauben, und in acht der 17 Länder, in denen die Wiederaufbereitung verboten ist.

Praktische Umsetzung von Artikel 17 MDR: Nur sechs der 42 befragten Benannten Stellen (NBs), die im Zusammenhang mit der MDR benannt wurden, gaben an, dass sie wiederaufbereitete SUDs oder die Wiederaufbereitung von SUDs zertifizieren. Die Gründe dafür, dass die meisten NBs keine Zertifizierung vornehmen, sind u. a. die fehlende Benennung für diese Tätigkeit, das Verbot der Wiederaufbereitung von SUDs im Land und das geringe Interesse der Kunden. Anträge auf Zertifizierung von SUDs wurden bisher nur in begrenztem Umfang gestellt; nur zwei NBs erhielten Anträge und bisher wurden keine Zertifikate für die Einhaltung der gemeinsamen Spezifikationen (CS) ausgestellt. Darüber hinaus berichteten die MFs und CAs über Schwierigkeiten bei der Identifizierung von NBs für die Zertifizierung von wiederaufbereiteten SUDs. Zum Zeitpunkt der Studie war kein NB qualifiziert, die Wiederaufbereitung gemäß Artikel 17(4) MDR (CS) zu zertifizieren. Darüber hinaus bereiten nur zwei identifizierte MFs (beide mit Sitz in Deutschland) SUDs auf dem EU-Markt tatsächlich wieder auf. Etwa die Hälfte (9 von 19) der HIs bereiten derzeit SUDs in Ländern auf, in denen die Wiederaufbereitung erlaubt ist, oder sie planen, dies zu tun. Als Gründe für die Nichtaufbereitung bzw. fehlende Weiterverwendung von wiederaufbereiteten SUDs nannten einige Gesundheitseinrichtungen einen begrenzten Nutzen, mangelnde Erfahrung mit der Aufbereitung, die Unmöglichkeit, eine Zertifizierung für die Einhaltung der CS zu erhalten, sowie Sicherheitsbedenken.

Herausforderungen und Vorteile: Die Konsultationen mit den vier Interessengruppen ergaben eine Reihe von Herausforderungen und Vorteilen. Alle Interessengruppen brachten zum Ausdruck, dass potenzielle Gesundheitsrisiken für Patientinnen und Patienten durch wiederaufbereitete SUDs zu Unsicherheiten führen, wobei es unterschiedliche Auffassungen zur

Evidenz gibt. Insbesondere sei es auch eine Herausforderung, alle Vorfälle im Zusammenhang mit wiederaufbereiteten SUDs in den nationalen Überwachungssystemen korrekt zu erfassen. Die Eignung einiger Produkte für die Wiederaufbereitung ist unter den Beteiligten umstritten; es gibt ethische und rechtliche Bedenken sowie Zweifel an der Wiederaufbereitung als Konzept an sich. Umgekehrt sehen die Beteiligten Kosteneinsparungen und Umweltvorteile als positive Aspekte einer Wiederaufbereitung von SUDs.

Von den Stakeholderinnen und Stakeholdern empfohlene Maßnahmen und laufende Diskussionen: Zu den möglichen, von den Interessengruppen vorgeschlagenen Maßnahmen, um die Wiederaufbereitung von SUDs weiter zu fördern, gehören die Verschärfung der rechtlichen Anforderungen (um Klarheit und ein gemeinsames Verständnis zu schaffen), die Einführung eines klaren Rückverfolgungssystems (um die Risiken zu verringern) sowie verbesserte Schulungen und ein verbessertes Risikomanagement. Die Beteiligten sind sich darin einig, dass durch wissenschaftliche Studien und Diskussionen in Expertengruppen zusätzliche Erkenntnisse gewonnen werden müssen. In mehreren Ländern wird eine politische Debatte über die mögliche Zulassung der Wiederaufbereitung von SUDs geführt, wobei die Schaffung von Evidenz in Form von wissenschaftlichen Studien und gesetzlichen Änderungen erwogen wird.

Schlussfolgerungen

Die Analyse, wie die in Artikel 17 MDR festgelegten Bestimmungen von den untersuchten Ländern umgesetzt wurden, zeigt ein **sehr unterschiedliches Bild**: Nur zehn Länder erlauben die Wiederaufbereitung von SUDs. Da es nur sehr wenige Studien zu diesem Thema gibt, besteht ein Bedarf an weiteren Erkenntnissen, die auch die Entscheidungen über die Zulassung oder das Verbot der Wiederaufbereitung von SUDs unterstützen könnten. Die **Fragmentierung und Komplexität der Umsetzung** aufgrund der verschiedenen nationalen Vorschriften führt zu einer potenziellen Wissenslücke bei den MFs und HIs hinsichtlich des rechtlichen Rahmens der Wiederaufbereitung in den verschiedenen Ländern. Da außerdem nur **wenige NBs wiederaufbereitete SUDs zertifizieren** und da bisher kein MDR-Zertifikat ausgestellt wurde, wurde der begrenzte Zugang zur Zertifizierung als Engpass identifiziert.

Empfehlungen

Auf Basis der im Rahmen der Studie gesammelten Evidenz einschließlich der Einsichten aus den Umfragen und Interviews mit den vier Hauptakteuren wurden **17 Empfehlungen zu fünf Themenbereichen** entwickelt und geclustert, um Hindernisse bei der Umsetzung von Artikel 17 MDR zu beseitigen. Zu den **allgemeinen Empfehlungen** gehören die Förderung weiterer Evidenz durch gezielte Forschungsprogramme, die von den zuständigen Behörden oder auf EU-Ebene initiiert werden sollten, sowie eine Verbesserung der Klarheit und Transparenz der nationalen Umsetzung von Artikel 17 MDR. In Bezug auf die **rechtlichen EU-Rahmendokumente** wird empfohlen, Leitfäden (z. B. ein Q&A-

Dokument) für die wichtigsten Zielgruppen zu erstellen, die idealerweise eine Schritt-für-Schritt-Anleitung für die Umsetzung von Artikel 17 MDR und insbesondere der CS enthalten. Um Hindernisse im **Zertifizierungsprozess** zu beseitigen, wird empfohlen, darüber zu informieren, welche NBs für die Zertifizierung von wiederaufbereiteten SUDs zuständig sind, und die Zertifizierung für die Einhaltung der CS zu verdeutlichen. Es ist von entscheidender Bedeutung, dass die **Mitgliedstaaten in verschiedenen Bereichen gezielte Maßnahmen ergreifen**, um die Maßnahmen der EC zu unterstützen und zu ergänzen, z. B. durch Informationskampagnen oder Capacity-Building-Maßnahmen in den HIs. Zu den **produktbezogenen Empfehlungen** gehört die Ausarbeitung von Leitfäden zur Eignung verschiedener Arten von SUDs für die Wiederaufbereitung.

Stichworte

Verordnung (EU) 2017/745 über Medizinprodukte, MDR, Artikel 17, Einwegprodukte, Wiederaufbereitung, Weiterverwendung

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Abbreviation	Explanation
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios / Spanish Agency for Medicines and Medical Devices
AFMPS	Federal Agency for Medicines and Health Products (Belgium)
AGES	Austrian Agency for Health and Food Safety GmbH (Austria)
AMDR	Association of Medical Device Reprocessors
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France)
BfArM	Federal Institute for Drugs and Medical Devices (Germany)
CA(s)	Competent Authority/Authorities
CfSH	Centre for Sustainable Hospitals
CS	Common Specifications
DG SANTE	Directorate-General for Health and Food Safety (at the European Commission)
DGS	Direction générale de la santé (France)
DMIDS	Deutsches Medizinprodukte-Informations- und Datenbanksystem / German Medical Devices Information and Database System
DKMA	Danish Medicines Agency
EC	European Commission
ECG / EKG	Electrocardiogramm / Elektrokardiogramm
EEA	European Economic Area
EMDN	European Medical Device Nomenclature
EP	Electrophysiology
EU	European Union
EUDAMED	European database on medical devices
FAQ	Frequently asked question
FDA	Food and Drug Administration (United States of America)

Abbreviation	Explanation
FIMEA	Finnish Medicines Agency
FSCA	Field Safety Corrective Actions
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency
HALMED	Agency for Medicinal Products and Medical Devices (Croatia)
HI(s)	Health institution(s)
HOPE	European Hospital and Healthcare Federation
HPRA	Health Products Regulatory Authority (Ireland)
IVO	Inspektionen för vård och omsorg / Swedish Health and Social Care Inspectorate
MD(s)	Medical device(s)
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation)
MF(s)	Manufacturer(s)
MPDG	Medizinprodukterecht-Durchführungsgesetz / German Medical Devices Implementation Act
MS(s)	Member State(s)
NB(s)	Notified Body/Bodies
NSAI	National Standards Authority of Ireland
PPRI	Pharmaceutical Pricing and Reimbursement Information
QMS	Quality management system
SMCS (former: NANDO)	Single Market Compliance Space (former: New Approach Notified and Designated Organisations)
SME(s)	Small and medium-sized enterprise(s)
SO(s)	Study objective(s)
SOP	Standard operating procedure
SQ(s)	Study question(s)

Abbreviation	Explanation
SUD(s)	Single-use device(s)
US	United States (of America)
UZA	University Hospital Antwerp
WFHS	World Federation for Hospital Sterilisation Sciences
WHO	World Health Organization
ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (Germany)

1. Introduction

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (Medical Device Regulation – MDR) is **directly applicable EU legislation** with relevance for the European Economic Area (EEA)[1]. However, there are topics that Member States regulate by national law. This applies to **Article 17 MDR**, which introduced new **legal requirements for single-use devices (SUDs) and their reprocessing** and which **may only take place where permitted by national law and in accordance with this Article**. This leads to a diverse picture across the EEA countries.

In December 2022, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via the European Health and Digital Executive Agency (HaDEA) – commissioned a **Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market** as part of the EU4Health Programme from a consortium led by the **Austrian National Public Health Institute** (Gesundheit Österreich GmbH/GÖG), in collaboration with **S&P Global**, **Areté** and **Civic Consulting** (specific contract No 2021 P3 04 and implementing framework contract No SANTE/2021/OP/0002).

The study took place over a period of **14 months** (from 15 December 2022 to 14 February 2024). Its aim was to **evaluate** how the **provisions** established in **Article 17 MDR have been implemented by the 27 Member States** of the European Union (EU) and three EEA countries **Iceland**, **Liechtenstein** and **Norway** and to understand how such provisions operate in practice.

The data collected in this study were intended to **reflect the situation of the reprocessing and reuse of SUDs on the European market up to the end of 2023**. As such, the data allow an assessment of the situation up to about two and a half years after the MDR entered into force (24 May 2021).

This document constitutes the **final report** of the study. The background, scope of the study, objectives and study questions are described in Chapter 1. The methodological approaches are presented in Chapter 2. The findings of the study (regulatory framework and practical implementation as well as challenges, opportunities, actions and ongoing discussions mentioned by the stakeholders) are provided in Chapter 3. Conclusions are set out in Chapter 4 and recommendations in Chapter 5. Chapter 6 lists the references. Additional documents and information are provided in the Annexes.

1.1. Background

Since 26 May 2021, the MDR has been fully applicable and serves as a regulatory framework for medical devices in the EEA to improve the quality, safety and reliability of medical devices; to strengthen transparency and information for patients; and to enhance vigilance and market surveillance [1].

Article 17 of the MDR sets out the legal requirements for **single-use devices and their reprocessing** (see Annex I for the full Article), which leaves the decision on authorisation or prohibition up to the EU Member States but only in accordance with the requirements in this Article. It contains **two different reprocessing options**:

- Any natural or legal person who reprocesses a SUD shall be considered to be the **manufacturer** (MF) of the reprocessed device and shall assume the obligations incumbent on MFs.
- Any health institution (HI) that reprocesses and uses a SUD in-house must comply with **common specifications** (CS).

To facilitate understanding of this report, the paragraphs of Article 17 MDR are briefly outlined:

Article 17(1) MDR points out the national regulatory responsibility for the topic (see Box 1).

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Article 17(1) of Regulation (EU) 2017/745

Box 1: Article 17(1) of Regulation (EU) 2017/745

*'Reprocessing and further use of single-use devices may only take place **where permitted by national law** and only in accordance with this Article.'*

Source: Article 17(1) of Regulation (EU) 2017/745

Article 17(2) MDR lays down that the reprocessor becomes the MF through reprocessing, with all the associated rights and obligations: *'Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The*

reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.'

Article 17(3) MDR regulates the special provisions for SUDs that are reprocessed and used within HIs in accordance with the Commission Implementing Regulation (EU) 2020/12072 (Common Specifications). This Implementing Regulation sets out specific requirements and procedures (e.g. quality management systems, labelling, traceability, vigilance, staff, premises and equipment). The procedures apply both in the case of reprocessing done in-house or sub-contracted to an external entity. In the latter case, there are also specific requirements related to the contractual arrangements between the HI and the external reprocessor.

Article 17(4) MDR suggests that Member States also extend the provisions in paragraph 3 to external reprocessors assisting HIs with the reprocessing of a SUD according to the CS at the request of a HI if the reprocessed device is returned to that HI.

Article 17(5) MDR includes information on the adoption of the necessary CS for Article 17(3) which should be *'in accordance with the latest scientific evidence and shall be consistent with the application of the general safety and performance requirements'* laid down in the MDR.

Article 17(6) MDR regulates which devices are permitted to be reprocessed and states that *'only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2021 in accordance with Directive 93/42/EEC, may be reprocessed.'*

Article 17(7) MDR states that *'only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.'*

Article 17(8) MDR requires that the name, address and other relevant information of the reprocessor must be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

Article 17(9) MDR addresses the regulations on reprocessing by Member States and points out that stricter provisions (than those in the Regulation) may also

apply. Member States must notify the Commission of them. It also stipulates that the Commission must make this information publicly available[2].

Article 17(10) MDR states that *'the Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. Based on that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.'*

The definitions of **single-use device**, **reprocessing** and the **common specifications** which are set out in Article 2 MDR are provided in Box 2 below. In addition, a study-specific glossary comprising 69 terms can be found in Annex II; this was also published[3] as a working document during the study to support stakeholders' common understanding of the terms. The study was summarised in two published one-pagers (see Annex III) to support its visibility and clearly present its aim and scope.

Box 2: Selected definitions

*'**Single-use device** means a device that is intended to be used on one individual during a single procedure.'*

Source: Article 2(8) of Regulation (EU) 2017/745

*'**Reprocessing** means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.'*

Source: Article 2(39) of Regulation (EU) 2017/745

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Single-use devices

*'**Common specifications (CS)** means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.'*

Source: Article 2(71) of Regulation (EU) 2017/745

[2] The European Commission has already published an overview of national rules on reprocessing of SUDs on their website.

[3] https://ppri.goeg.at/Study_Article17MDR

1.2. Scope of the study

The study specified the stakeholder groups, countries and products involved as follows:

Key stakeholders: the perspectives of **four key stakeholders** were collected and analysed in order to **evaluate the functioning and implementation of the provisions** established in Article 17 MDR as well as to provide a comprehensive mapping of the current market situation for the reprocessing/reuse of SUDs in Europe:

- **Competent authorities (CAs)** on MDs of the 27 EU Member States, Iceland, Liechtenstein and Norway;
- **Notified bodies (NBs)** designated under the MDR;
- **Manufacturers (MFs)** that reprocess SUDs;
- **Health institutions (HIs)** that reprocess and reuse SUDs.

Country scope: the study covered a total of **30 European countries** comprising the **27 EU Member States** and three European Economic Area (EEA) countries **Iceland**, **Liechtenstein** and **Norway**. In the report these are referred to as 'study countries'.

Product scope: **only SUDs** fall within the **scope of this study. Reusable devices** (such as surgical instruments, arthroscopic instruments and pelvis copes) **are not considered**. Products were clustered according to their purpose (e.g. orthopaedic equipment, catheters) or the first four digits of the European Medical Device Nomenclature (EMDN) codes. The following SUDs were considered in this study:

- **Product types:** CE marked devices intended for single use

  [Note: Reprocessing can be carried out on MDs, accessories for MDs or Annex XVI products (cf. Article 1(4) MDR)];
- **Market status:** devices available on the EU market;
- **Risk classes:** devices belonging to all risk classes (if reprocessed).

1.3. Study objectives

The study **evaluates how the provisions established in Article 17 MDR have been implemented** in the study countries and how such provisions operate.

This general objective was addressed by **five specific objectives (SOs):**

- **SO1:** to quantify the reprocessors operating in each Member State, to identify the types of SUDs reprocessed and to estimate the quantities reprocessed per year per type;
- **SO2:** to quantify the certificates issued by NBs to confirm compliance with the Common Specifications (CS);
- **SO3:** to develop a dashboard, including relevant indicators for all Member States permitting reprocessing at national level, consisting of tables, graphs and other tools useful for showing the results of the collected data and information in a stratified manner;
- **SO4:** to identify and analyse challenges and obstacles (e.g. national restrictions/prohibitions, NB availability or capacity, regulatory requirements, and related costs) that could affect the reprocessing of SUDs;
- **SO5:** to present the outcomes of the analysis in a report with user-friendly layout, including infographics and possible solutions/recommendations for removing obstacles and challenges, also considering their dissemination among stakeholders and the general public.

1.4. Study questions

Based on the study objectives, **three main study questions (SQs)** were defined along with detailed sub-questions:

SQ1: what is the current situation in the EU for the reprocessing of SUDs?

Regarding EU Member States (and further countries in the scope of the study):

- How many study countries prohibit the reprocessing of SUDs?

- If the reprocessing of SUDs is permitted, what is the legal basis in each Member State, and what do the provisions regulate?
- How many study countries transfer SUDs to other Member States or non-EU countries? To which EU Member States and/or non-EU countries are reprocessed SUDs transferred (if permitted, by Member State)?
- How many study countries make SUDs available for further reuse after reprocessing?

How many and which types of reprocessors operate in the EU?

- How many HIs carry out reprocessing according to the CS in each Member State?
- How many external reprocessors carry out the reprocessing of SUDs according to the CS at the request of a HI?
- How many MFs reprocess SUDs in each Member State? Are there MFs specialised in the reprocessing of SUDs?
- Are there any other types of reprocessors, and if so, which types and how many per Member State?

What kinds of SUDs are reprocessed?

What are the estimated quantities reprocessed?

- What are the estimated quantities of SUDs that are reprocessed and reused within the EU?
- What are the estimated quantities of SUDs that are reprocessed and reused in non-EU countries (and in which, if possible)?
- How many certificates are issued by NBs to confirm compliance with the CS?
- How many NBs per Member State are in place? Are there NBs specialised in reprocessing?
- How many certificates have been issued by NBs for reprocessed SUDs (if possible, per Member State)?

SQ2: which obstacles and challenges might affect the reprocessing of SUDs in the EU?

What are the general obstacles that could affect the reprocessing of SUDs in the EU?

- What are potential challenges for Member State regulatory authorities?
- What are potential challenges for MFs to place reprocessed SUDs on the market?
- What are potential challenges for HIs to re-use reprocessed SUDs, including possible issues arising from the requirements introduced by the MDR?
- What are potential challenges for NBs to certify that reprocessing is performed according to the CS?
- Which types of challenges (e.g. safety issues, processes, communication between stakeholders, organisational challenges, financial burdens) are most prominent?

SQ3: which possible solutions and recommendations could be used to address potentially identified issues?

What can be drawn from experience?

- Are there any best practice examples to address these or similar identified issues and obstacles at Member State level?
- Are there any discussions and plans at national level that aim to address identified or expected issues and challenges? What are the possible lessons learnt?
- Are there any potential lessons learnt concerning policy measures and approaches in other or related areas (e.g. other health products) which aimed to address different components of access and availability?
- Which solutions could be taken to optimise the reprocessing of SUDs and their use within the EU?
- Which solutions could be a ‘quick win’, and which policy measures would require more complex preparation?

Which recommendations can be developed?

- How can recommendations be best addressed / targeted at the different stakeholder groups involved (CAs, MFs, HIs and NBs) to optimise the reprocessing of SUDs and their use within the EU?

2. Methodology

The study used a **mixed-method approach**, including data and information collection via a **literature review** and **stakeholder engagement** in the form of **targeted surveys** and **interviews** (exploratory and follow-up interviews), to collect primary data for the analysis. This chapter provides an overview of all of the methodological approaches applied in this study.

Triangulation of methods was used across the study. Table 1 provides an overview of the **mix of qualitative and quantitative methods** applied to address the three study questions and the results presented in this report as well as a **dashboard** that was developed in the course of the study for an interactive display of the information collected (see Chapter 2.3.).

Table 1: Triangulation of study questions and methodology

Study questions (SQs)	(Grey) literature review	Stakeholder consultation			Presentation of findings in the dashboard
		Exploratory interviews	Surveys	Follow-up interviews	
SQ1: what is the current situation in the EU for the reprocessing of SUDs?	Supplementary data source	Supplementary data source	Major data source	Supplementary data source for back-up and to increase coverage of surveys	yes
SQ2: which obstacles and challenges might affect the reprocessing of SUDs in the EU?	Supplementary data source	Supplementary data source	Major data source	Supplementary data source for back-up and to increase coverage of surveys	yes
SQ3: which possible solutions and recommendations could be used to address potentially identified issues?	Supplementary data source	Supplementary data source	Major data source	Supplementary data source for back-up and to increase coverage of surveys	yes

Source: the contractor

The **surveys were the main data source** for the study, supplemented by the other methodological approaches (literature review, exploratory and follow-up interviews). In the inception phase of the study, the literature search was conducted to identify already published data and information on this topic. The knowledge acquired through the **exploratory interviews** formed the basis for the creation of the surveys and interview guides for the activities engaging the

stakeholder groups. The **follow-up interviews** supplemented the information and data collected through the surveys and allowed the study team to back up or clarify any information previously collected.

Table 1 also shows that all of the data are presented in the **dashboard**, offering a quick and visual overview of the implementation of Article 17 MDR on SUDs (see Chapter 2.3).

2.1. Literature review

The collection of literature was a horizontal task performed for the duration of the study. An extensive preliminary literature review was conducted during the inception phase and complemented with additional pieces of literature identified during the study period. The aim of the literature review was to identify:

- **peer-reviewed literature** (scientific articles) as well as
- **grey literature** (e.g. legislation and guidance documents, position papers, reports of international organisations and interest associations, outcomes of surveys and consultation activities, statistics).

Relevant documents were identified through a targeted search on PubMed and Google Scholar as well as through recommendations from different stakeholders. While peer-reviewed literature mainly provided insights into the effectiveness, risks and benefits of reprocessing SUDs, grey literature provided further understanding of the current state of national regulations and the perspectives of stakeholders regarding reprocessing. The EC website was the main source of information on national regulations relating to the reprocessing of SUDs. A more detailed overview of the search strategy for the literature review is provided in Annex IV.

Several documents provided insights into understanding the legal context in the different countries, including national implementations of Article 17 MDR, manufacturers' obligations and outsourcing as well as restrictions and prohibitions.

The following criteria were applied for including literature:

- **Time:** literature/information published after May 2017 (as the new regulations for MD in the EU were published at this point);
- **Geography:** literature/information from the study countries;

- **Languages:** English and German literature (The main body of literature and information is available in English; the study team identified further relevant information in German. Some other languages were covered through interviews with experts from Member States that pointed the study team towards further literature in those languages).

The identified literature was analysed and summarised in a comprehensive table, which is included in Annex IV. The results of the literature review also provided the basis for the development of the surveys and interview guides used in the consultation activities. All of the references were included in an Endnote® database.

After an initial literature review at the beginning of the study, literature was continuously added throughout the study. In total **28 publications were included in the initial literature review, encompassing 16 scientific articles and 12 documents classified as grey literature.** Key results of the literature provided insights into challenges, benefits and considerations influencing permission for or restriction of reprocessing. A number of studies were also included evaluating the effectiveness of reprocessing different SUDs as well as stakeholder views on reprocessing. The grey literature mostly provided information on the regulatory framework on reprocessing in different countries. The main results of the literature review are described in Chapter 3.1., Annex IVb provides a more detailed overview of the findings from the literature review.

2.2. Consultation activities

The consultation activities in this study included **exploratory interviews**, **surveys** targeted at the different stakeholder groups and **follow-up interviews** to increase the coverage and depth of the survey results and to develop a dashboard. An extensive stakeholder mapping was carried out at the beginning of the study during the inception phase.

For the consultation activities, a set of performance indicators (process-oriented indicators, see Annex IX) were developed to assess and present the performance of the consultation activities.

2.2.1. Interviews

In the inception phase of the study, **exploratory interviews** were conducted: representatives of the four defined key stakeholder groups were contacted and invited to take part in the study. Besides the **equal distribution** of interviews **across the stakeholder groups**, the study team made sure to choose interviewees from a **range of different countries** with **different experience in reprocessing**. Interview guides for the different stakeholder groups were developed and provided to the agreed interview partners. The guides (see Annex VI) also included an **informed consent form**. The interviews were led in **English**, which did not present a barrier for information gathering. As alternatives, interviewees could take part in the interview in other languages (German, French, Italian, Spanish) or answer the questionnaire in written form instead. Short **summaries** of each interview were produced and sent for validation to the interview partners.

Sixteen stakeholders were contacted for the exploratory interviews. Table 2 provides an overview of the number of exploratory interviews. In total, **seven interviews** (each lasting approximately 30-60 minutes) were conducted. Additionally, one NB provided written feedback. Despite contacting five HIs, no interview partners were obtained.

Table 2: Overview of the completed exploratory interviews

Stakeholder group	Number of exploratory interviews conducted
Competent authorities	4
Notified bodies	1
Manufacturers	1
Health institutions	0
Other (e.g. representative organisations)	1
Total	**7**

Source: the contractor

Follow-up interviews were carried out with **selected stakeholders after the surveys**. The purpose of these interviews was to supplement the information and data collected through the four surveys so as to complete the evidence base required for the study (see Annex VI for the interview guides) as well as to clarify any questions resulting from previous stakeholder activities performed.

Follow-up interviews aimed to ensure:

- the **completeness and accuracy** of the responses provided in the online surveys;
- **full coverage of the countries in which legislation is in place** on the reprocessing of SUDs as well as an in-depth examination of the implementation of national provisions;
- **a more complete coverage of countries where there was an information gap** on the national implementation of Article 17 MDR; and
- **background and in-depth information on any solutions and recommendations** that were provided by stakeholders.

In view of the purpose of the follow-up interviews, the study team defined **six criteria** in relation to responses in the surveys[4] which were used to determine the number of interviews and to select appropriate target group. On this basis, initially 25–30 interviews were foreseen (in at least six Member States with national legislation in place and six countries where the implementation status was unclear). The initial target group was defined across countries and stakeholder groups, with the intention of finalising the exact coverage (i.e. countries, target groups, questionnaires to be used) in relation to responses in the surveys once they had closed.

The **interviews were conducted** from **May to October 2023** through online meeting platforms (MS Teams, WebEx, Zoom). Notes taken during the interviews were validated by the participants at each interview. An overview of the completed follow-up interviews is provided in Table 3Table 5. In total, **32 interviews** were conducted, including **30 organisations** from **11 countries** (Belgium, Croatia, Denmark, France, Germany, Ireland, the Netherlands, Norway, Slovenia, Spain, Sweden).

[4] The six criteria were: 1) overall response rate to the survey remains too low for the data/information needs of the study; 2) reponses are too incomplete to allow sufficient analysis; 3) responses contradict the evidence provided by another stakeholder (in the same country); 4) responses come from key targeted respondents to the survey, e.g. NBs, MFs, HIs, CAs; 5) responses come from countries with national legislation in place allowing the reprocessing of SUDs – since they are of more interest as a focus country; 6) Responses do not offer in-depth insights on solutions or recommendations as to how to improve the situation.

Table 3: Overview of the completed follow-up interviews

Stakeholder group	Number of follow-up interviews
Competent authorities[1]	12
Notified bodies	9
Manufacturers[2]	1
Health institutions	8
Other[3]	2
Total[4]	**32**

Notes:
[1] One more CA was interviewed in the exploratory phase; as their feedback was complete and fully aligned to the survey response, no further interview was undertaken with this CA.
[2] One further reprocessor declined the interview but provided written feedback.
[3] MedTech Europe: the European trade association representing the medical technology industry including diagnostics, MDs and digital health; AMDR: Association of Medical Device Reprocessors (US-based).
[4] Ten further organisations were approached for a follow-up interview. Six organisations declined for various reasons (mainly due to a lack of relevance). The four remaining organisations did not reply to the request for a follow-up interview.

Source: the contractor

Based on the interviews and the findings of the surveys, the study team notes that **the number of MFs reprocessing SUDs in the EU is very limited.** Only two companies in Germany were identified as being involved in the reprocessing of SUDs. Consequently, the number of interviews with reprocessors turned out to be lower than initially foreseen. **Interviews were also conducted with the associations representing MD MFs/reprocessors (MedTech Europe, AMDR)**; these interviews provided useful insights and the wider industry's perspective on the implementation of Article 17 MDR.

2.2.2. Surveys

The surveys were targeted at four stakeholder groups and carried out online.

Survey development: a major focus of the data collection was on conducting **targeted online surveys** for each of the **stakeholder groups defined** in the study. Based on the knowledge gained from the exploratory interviews and the literature review, a total of **seven different questionnaires** were developed to account for the different target groups within the four key stakeholder groups (see Annex VII). The draft questionnaires were **reviewed** by DG SANTE/HaDEA and

piloted with different institutions to allow for further adaptation and optimisation before the official launch. All surveys were hosted on the EUSurvey platform[5].

Survey launch and management: the set of **seven questionnaires in four online surveys** were launched **between mid-May and mid-June 2023**. Targeted stakeholders (NBs, CAs, MFs and HIs) were contacted via e-mail and asked to fill in the online survey. In the specific case of HIs, national associations were asked to disseminate the link and invitation within their countries. To ensure a high response rate, reminders and awareness-raising activities – such as individual phone calls – were conducted in the days leading up to the deadlines. These efforts aimed at achieving the highest possible number of responses. A set of **support mechanisms** was implemented, such as **contact points for help**, a **glossary** for the main terms used in the study and a **PDF version of the questionnaire with detailed instructions** (particularly useful to support the internal consultation process within companies/organisations).

Survey update: as the data collection in this study was intended to **reflect the situation up to the end of 2023**, a **survey update** was carried out with all CAs, NBs and MFs between November and December 2023 to inquire about any changes compared to the initial survey and to ascertain whether any anticipated changes were forthcoming (see Annex VIII). Additionally, four new NBs designated under the MDR were invited to fill in the survey. There were no changes expected from HI; hence this stakeholder group was not contacted again.

Survey performance results: surveys with all four stakeholder groups were completed between May and September 2023: provides an overview of the response rate by stakeholder group.

[5] https://ec.europa.eu/eusurvey/home/about

Table 4: Survey implementation and response rates

Stakeholder group	Online survey (EUSurvey tool)		Survey update (via email, phone calls and EUSurvey tool)	
	Survey period	Responses/ response rate	Survey period	Responses/ response rate
Competent authorities	12.6.2023 – 1.9.2023	30 out of 30 countries (100%)	7.11.2023 – 15.12.2023	27 out of 30 countries (90%)
Notified bodies[1]	14.5.2023 – 4.8.2023	38 out of 38 NBs (100%)	7.11.2023 – 15.12.2023	35 out of 42 NBs (83%)
Manufacturers[2]	24.5.2023 – 20.7.2023	2 out of 2 MFs[3]	23.11.2023 – 11.12.2023	2 out of 2 MFs[3]
Health institutions[4]	14.6.2023 – 8.9.2023	19 valid replies by HIs (no information about total number of HIs reprocessing/ reusing)[5]	n/a	n/a

n/a = not applicable (no survey update conducted)
[1] An information email was sent to NB representatives (NBCG and Team NB) to inform them about the study and the ongoing survey by the study team. DG SANTE informed members of the NBO subgroup.
[2] The survey was also sent to the national associations in six countries that allow reprocessing (Belgium, Croatia, Germany, Ireland, the Netherlands, Sweden) and to MedTech Europe with the request to circulate it among its members.
[3] The study team is not aware of any other MFs that reprocess SUDs. After consultation with the MFs and other stakeholder groups, no further companies were identified.
[4] The survey was sent for dissemination to 15 national associations of HIs in six Member States where the reprocessing of SUDs is allowed.
[5] 46 replies by health institutions were received, of which 27 (59%) had to be excluded (mostly empty replies).

Source: the contractor

In the first round of the survey, a **100% response rate** was achieved for **CAs** (30 out of 30 countries replied) and **NBs** (38 out of 38 replied). For **MFs** within the scope of the study, all companies identified and currently operating on the EU market responded to the survey. No information on the total number of **HIs** reprocessing SUDs in Europe is available; hence the exact response rate could not be determined.

For the **survey update**, 35 out of the 42 NBs contacted responded to the survey update. Among these, two NBs provided supplementary information, while the rest confirmed their initial survey responses. For CAs, a total of 27 out of 30 countries participated in the survey update. Among these, Denmark reported major changes, and some countries provided additional information or minor corrections; for all of the others, the responses from the initial survey remained applicable.

2.3. Development of a dashboard

A dashboard was developed in Microsoft© Power BI in the course of the study. Its aim is to provide an **easily understandable and interactive presentation of the main results of the study**. The dashboard includes a set of process and outcome indicators per stakeholder group (see Annex IX for details). Table 5 provides an overview of the dashboard pages and content.

Table 5: Dashboard pages and content

Dashboard page	Content
Home	Introductory information on the reprocessing and reuse of SUDs, background information on the study and the development of the dashboard
About	More detailed information about the project, data included and the surveys performed with the four stakeholder groups
Process indicators	Information on the process indicators (number of stakeholders contacted and the number of responses collected per stakeholder group)
Outcome indicators	Overview page for the outcome indicators presenting the results of the surveys and literature review as well as the outcome indicators by stakeholder group
Glossary/Links	Study-relevant terms (based on the glossary developed for the study) and a list of relevant links to downloads

Source: the contractor

The final version of the dashboard will be **published** and hosted by DG SANTE (screenshots of the final version are provided in Annex X). It aims to support the dissemination of this report and its results.

3. Results

This chapter combines the results of:

- the **literature review**;
- the **results of the first round of the survey** with all four stakeholder groups via the EUSurvey tool and the **survey update** to collect information reflecting the situation up to 31 December 2023;
- and the information gathered in the **preliminary and follow-up interviews**.

The information shown in the next sub-chapters corresponds to the situation as of 31 December 2023.

3.1. Insights from the literature

Key results of the literature review provide insights into **challenges**, **benefits**, and **considerations influencing the authorization or restriction of reprocessing**. Reasons for supporting reprocessing include economic and environmental benefits [3, 4]. **Environmental impact studies** on reprocessing SUDs revealed a nearly 50% reduction in long-term emissions per catheter life, along with a reduced impact on global warming and improved utilisation of resources [6, 7]. Conversely, **concerns about reprocessing stem from insufficient testing data on safety and efficacy**.

Some studies, however, indicate **safety comparable to new devices**. For instance, a report from Sweden considers reprocessing – under strict regulations – as safe, with no significant safety differences between reprocessed and new products [5]. Another study found that **policy makers tend to prefer single-use disposables for their perceived safety benefits** [15].

Challenges with SUDs include **potential health risks, changes to devices through reprocessing, liability issues and ethical considerations** such as patient consent and equal access to treatment [8-10].

Stakeholder perspectives on reprocessing vary, with industry favouring reprocessing to reach new markets [11] and HIs expressing concerns about liability and costs [12].

A number of studies also explored the **perspective of healthcare personnel on reprocessing**. A survey conducted among electrophysiologists indicated a favourable view of this group towards reprocessing SUDs, particularly commonly used instruments such as electrophysiological catheters and cables [13]. Another survey, which explored the views of Croatian surgeons on reprocessing SUDs, showed that nearly all of them practised the reuse of single-use surgical instruments, with only a few being aware of the legal situation in their country concerning the reprocessing of SUDs [14].

Recommendations as identified in the literature highlight the necessity for **robust risk management plans and detailed regulatory requirements** as well as the need to **involve all stakeholders in determining policy** for reprocessing SUDs [8, 16, 17].

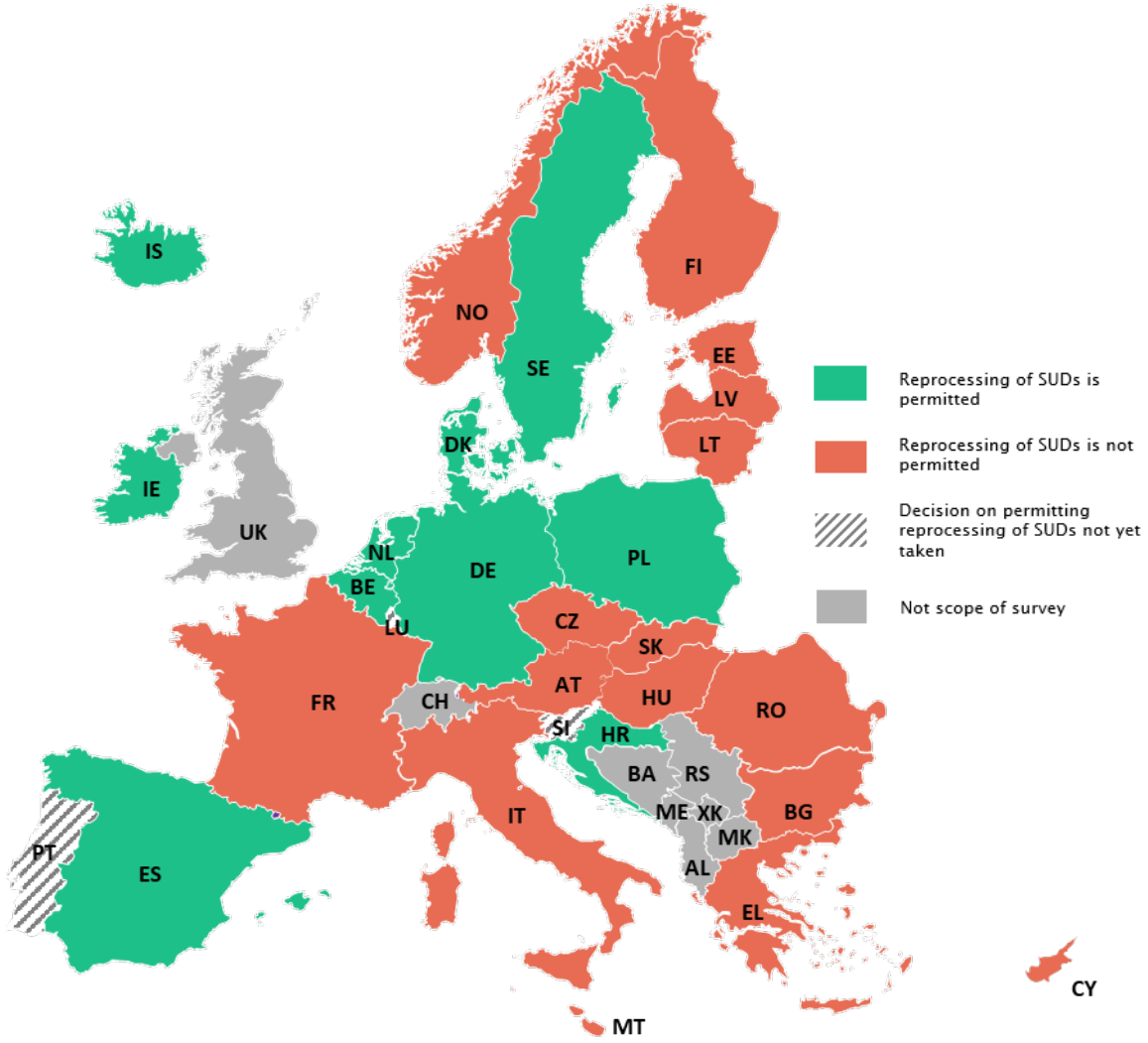
As regards regulatory aspects, challenges may result from unclear policies and varying interpretations (i.e. due to the subsidiary nature of the MDR where the decision to allow or prohibit reprocessing lies with individual Member States), leading to potential confusion and dissatisfaction among stakeholders [18].

However, the literature suggests that certain **stakeholder groups, such as medical doctors, may still have a positive attitude toward the reprocessing of SUD**, even though there seems to be a potential knowledge gap regarding the legal context of reprocessing [14].

3.2. Regulatory implementation of Article 17 MDR in national provisions

As set out in Chapter 1.1., Article 17 MDR allows Member States to decide whether to allow the reprocessing of SUDs at national level. The survey of CAs revealed a very diverse picture across the study countries (see Figure 1).

Figure 1: Overview of study countries relating to the reprocessing of SUDs



Country abbreviations: AL = Albania, AT = Austria, BE = Belgium, BG = Bulgaria, CH = Switzerland, CY = Cyprus, CZ = the Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IS = Iceland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, ME = Montenegro, MD = Moldova, MK = North Macedonia, MT = Malta, NL = the Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, RS = Republic of Serbia, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom, XK = Kosovo

Source: CA survey (2023)

Figure 1 shows that:

- **17 out of 30 countries** (Austria, Bulgaria, Cyprus, the Czech Republic, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Liechtenstein, Lithuania, Malta, Norway, Romania, Slovakia) indicated that

reprocessing according to Article 17(2) MDR and/or compliance with the CS according to Article 17(3) MDR **is <u>not</u> allowed**;

- **10 out of 30 countries** (Belgium, Croatia, Denmark[6], Germany, Iceland, Ireland, the Netherlands, Poland[7], Spain, Sweden) stated that **reprocessing is allowed**;
- **3 out of 30 countries** (Luxembourg, Portugal, Slovenia) **have not yet made a decision** on prohibiting or allowing reprocessing in their country.

The reasons given for **not having made a decision** include the **varying opinions of stakeholders** and **bureaucratic efforts required**. The competent authority from **Luxembourg** indicated that reprocessing would most likely be prohibited due to perceived safety reasons, potential liability issues and potential health hazards. Arguments in favour of allowing reprocessing in Luxembourg were mainly for economic and environmental benefits. The competent authority from **Portugal** expected that reprocessing would be allowed in the future. The competent authority from **Slovenia** reported that no national provision had been adopted so far and gave no indication as to whether reprocessing might be permitted in the future or not.

3.2.1. National provisions regulating the reprocessing and further use of single-use devices

Table 6 shows the **national provisions regulating the reprocessing and further use of SUDs** in accordance with Article 17(1) MDR in the **nine countries** where **reprocessing is currently allowed**. Information on Denmark (the tenth country where reprocessing will become allowed) is not yet available as the country is currently developing national provisions.

[6] While in the first survey round **Denmark** stated that the decision on allowing reprocessing had not yet been made, in the survey update it was stated that they now had the political mandate to allow the reprocessing of SUDs and that they were in the process of developing national rules (in the form of executive orders to their national legislation acts).

[7] In **Poland**, the reprocessing of SUDs has not been prohibited as this would restrict freedom of economic activity. However, the use of such devices in Poland was prohibited for safety reasons.

Table 6: National provisions regulating the reprocessing and further use of SUDs

Country	Name of national provision(s) in national language and in English (including link)	Paragraph in the national provision(s) regulating the reprocessing of SUDs	Date when the national provision(s) entered into force
Belgium	Loi relative aux dispositifs médicaux **(Law on medical devices)**	**Article 12**	**26.5.2021**
	Arrêté royal portant exécution de la loi du 22 décembre 2020 relative aux dispositifs médicaux **(Royal Decree implementing the law of 22 December 2020 on medical devices)**	**Articles 6 and 7**	**26.5.2021**
Croatia	Zakon o provedbi Uredbe (EU) 2017/745 o medicinskim proizvodima i Uredbe (EU) 2017/746 o in vitro dijagnostičkim medicinskim proizvodima (Narodne novine, br. 100/18.) **(Act Implementing Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (Official Gazette No 100/18)**	**Article 13**	**22.11.2018**
Germany	Gesetz zur Durchführung unionsrechtlicher Vorschriften betreffend Medizinprodukte (Medizinprodukterecht-Durchführungsgesetz – MPDG) **(Medical Devices Implementation Act)**	**§§ 17b and 77**	**26.5.2021**
	Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten (Medizinprodukte-Betreiberverordnung – MPBetreibV) **(Ordinance on the installation, operation and use of medical devices (Medical devices operator ordinance))**	**§§ 5 and 8**	**7.7.1998, revised on 21.8.2002; last amended on 21.4.2021**
Iceland	Lög um lækningatæki 132/2020 **(Act on medical devices No 132)**	**Article 18**	**26.5.2021**
Ireland	**National Statutory Instrument SI No.261 of 2021 Medical Devices Regulations 2021**	**Part 2 Regulation 7(1) and (2)**	**26.5.2021**
Netherlands[1]	Wet medische hulpmiddelen **(Law on medical devices)**	**Article 5**	**26.5.2021**
	Besluit medische hulpmiddelen **(Decision on medical devices)**	**Articles 4 and 5**	**26.5.2021**

Country	Name of national provision(s) in national language and in English (including link)	Paragraph in the national provision(s) regulating the reprocessing of SUDs	Date when the national provision(s) entered into force
Poland	Ustawa z dnia 7 kwietnia 2022 r. o wyrobach medycznych (Dz.U. 2022 poz. 974) **(Act of 7 April 2022 on medical devices (Journal of Laws 2022, item 974))**	**Article 17(1)**	**26.5.2022**
Spain	Real Decreto 192/2023, de 21 de marzo, por el que se regulan los productos sanitarios **(Royal Degree 192/2023 for medical devices)**	**Articles 11 to 15 and some points in Articles 7 and 18**	**22.3.2023[2]**
Sweden	Lag (2021:600) med kompletterande bestämmelser till EU:s förordningar om medicintekniska produkter **(Law (2021:600) complementing EU regulations on medical devices)**	**4 kap. 2 § 3** **7 kap. 4 §, 11 §**	**26.4.2022**
	Förordning (2021:631) med kompletterande bestämmelser till EU:s förordningar om medicintekniska produkter **(Ordinance (2021:631) complementing EU regulations on medical devices)**	**4 kap** **5 kap. 2 § 3** **7 kap. 2 §, 2 a §**	**26.4.2022**
	HSLF-FS 2023:16 Inspektionen för vård och omsorgs föreskrifter om reprocessares och externa reprocessares skyldighet att lämna uppgifter för registrering avseende sin verksamhet och sin produkt **(IVO regulation HSLF-FS 2023:16 health and social care inspectorate regulation on reprocessors' and external reprocessors obligations to give information on their organisation and products)**	**entire provision**	**1.7.2023**

Abbreviations: Kap = Kapitel (Swedish) / chapter (English)

Notes:
[1] The proposal for the change in legislation will be decided upon in the third week of January 2024.
[2] The date only applies to MFs; hospitals and external reprocessors are not allowed to reprocess SUDs.

Source: CA survey (2023)

Other national provisions, guidelines and specifications

In addition to the national provisions regulating the reprocessing and further use of SUDs in accordance with Article 17(1) MDR, **Germany, Iceland, Ireland**, and the **Netherlands** provided information on **further relevant national provisions, specifications or further documents** (e.g. guidelines) related to the reprocessing of SUDs:

- **Germany:** Joint recommendation of the Robert Koch Institute and the BfArM on hygiene requirements for the reprocessing of medical devices (so-called RKI-BfArM recommendation);
- **Iceland:** 1154/2021 Regulation on the reprocessing of single-use medical devices;
- **Ireland:** Health Service Executive (HSE)'s Medical Devices/Equipment Management Policy (Incorporating the Medical Devices Management Standard);
- **Netherlands:** Guidance on the re-sterilisation of single-use medical devices created by the Dutch association of experts on sterile medical devices.

Decision basis for authorising the reprocessing of SUDs

In **Ireland**, the **Netherlands** and **Sweden**, the decision to allow reprocessing was based on previous studies[8]. In **Belgium**, **Croatia** and **Spain**, national political debates led to the final decision.

[8] **Ireland:** Link not publicly available. In 2023 Ireland was in the process of conducting a new study, coordinated by the CA, to evaluate the national policy on reprocessing SUDs. In this context, the CA commissioned a synthesis review of evidence available on the cost, safety, and environmental impacts of reprocessing SUDs, which is nearing completion. The evaluation was prompted by a commitment to do this when the decision was taken in 2021 to opt into Article 17(2) MDR.
Netherlands: Nulmeting herverwerking medische hulpmiddelen voor eenmalig gebruik (2017): https://www.medassort.nl/wp-content/uploads/rapport_nulmeting_herverwerking_suds_scherm.pdf
Sweden: Förutsättningar för att reprocessa och återanvända medicintekniska engångsprodukter i Sverige (2020): https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2020-12-7158.pdf

Iceland had allowed reprocessing in the past (prior to the MDR); hence this decision and practice was maintained.

In **Poland** public consultations were carried out during work on the draft act on MDs. Article 22 of the Constitution of the Republic of Poland of 2 April 1997 indicates that limitations on the freedom of economic activity may be imposed only by means of statute and only for important public reasons. Therefore the reprocessing of SUDs has not been prohibited as this would restrict freedom of economic activity. However, making available and using such devices in Poland was prohibited for safety reasons.

In **Germany** the reprocessing of MDs (including SUDs) had already been permitted before the implementation of the MDR, with strict national rules applied to ensure that the reprocessed device is safe and functional. A key consideration was that reprocessed devices would contribute to cost savings for the healthcare system. During the negotiations on Regulation (EU) 2017/745 (MDR), Germany had advocated that the reprocessing of SUDs should be permitted for cost reasons as long as this is done safely. According to the information provided by the national CA, preliminary studies, national debates or other scientific evidence to justify the decision are not publicly available.

Options, restrictions and prohibitions in accordance with Article 17 MDR

Article 17 MDR provides for **specific options**, **restrictions**, or **prohibitions** for some countries, as shown in Table 7. Information on Denmark is not yet available.

Table 7: Options, restrictions, and prohibitions according to Article 17 MDR

Country	MF obligations[1] Country decided to apply Article 17(2) MDR	Common specifications[2] Country decided not to apply all of the rules laid down in Article 17(2) MDR	Outsourcing[3] Country decided to apply Article 17(3) MDR	Patient information[4] Country requires health institutions to provide information to patients	Restrictions and prohibitions[5] Country imposed restrictions and prohibitions
Belgium	yes	yes	yes	yes	yes
Croatia	no	yes	yes	yes	yes
Germany	yes	yes	yes	no	yes
Iceland	yes	no	yes	no	no
Ireland	yes	no	no	no	no
Netherlands	yes	no	no	no	yes
Poland	yes	no	no	no	yes

Country	MF obligations[1] Country decided to apply Article 17(2) MDR	Common specifications[2] Country decided not to apply all of the rules laid down in Article 17(2) MDR	Outsourcing[3] Country decided to apply Article 17(3) MDR	Patient information[4] Country requires health institutions to provide information to patients	Restrictions and prohibitions[5] Country imposed restrictions and prohibitions
Spain	yes	yes	yes	yes[6]	yes
Sweden	no	yes	yes	no	yes

Notes:
[1] Article 17(2) MDR applies in the country
[2] Country decided not to apply all of the rules relating to MFs' obligations as laid down in Article 17(2) MDR provided that the reprocessing is performed in accordance with Regulation (EU) 2020/1207 (CS)
[3] Country chose to apply the provisions regarding SUDs that are reprocessed by an external reprocessor at the request of a HI according to Article 17(4) MDR provided that the reprocessed device in its entirety is returned to that HI and the external reprocessor complies with the requirements referred to in Article 17(3) points (a) and (b) MDR
[4] Country requires HIs to provide information to patients on the use of reprocessed devices within the HI and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with
[5] National provisions include stricter restrictions and prohibitions in accordance with Article 17(9) MDR
[6] Article 15.3 of RD 192/2023 Royal Degree 192/2023 for MDs

Source: CA survey (2023)

Manufacturers' obligations: except for Croatia and Sweden, all countries that allow reprocessing decided to apply Article 17(2) MDR whereby any natural or legal person who reprocesses a SUD shall be considered the MF of the reprocessed device and shall assume the obligations incumbent on MFs as laid down in the MDR.

Common specifications: by way of derogation from Article 17(2) MDR, regarding SUDs that are reprocessed and used within a HI, Member States may decide not to apply all of the rules relating to MFs' obligations as laid down in the MDR. Belgium, Croatia, Germany, Spain, and Sweden opted for this approach, while Iceland, Ireland, the Netherlands and Poland did not do so.

Outsourcing: Belgium, Croatia, Germany, Iceland, Spain and Sweden chose to apply the provisions regarding SUDs that are reprocessed by an external reprocessor at the request of a HI according to Article 17(4) MDR provided that the reprocessed device in its entirety is returned to that HI and the external reprocessor complies with the requirements referred to in Article 17(3) points (a) and (b) of the MDR.

Patient information: Belgium, Croatia and Spain require HIs to provide information to patients. Only Spain has a dedicated regulation on this aspect. Germany noted that HIs are legally bound to give all relevant information to patients.

Restrictions and prohibitions: seven countries (Belgium, Croatia, Germany, the Netherlands, Poland, Spain, Sweden) introduced national provisions that are stricter than the MDR:

- In **Belgium** national provisions stipulate that certain devices are banned from reprocessing, e.g. SUDs with non-removable batteries and/or where data cannot be cleared, SUDs emitting ionising radiation or implantable devices. These restrictions are laid out in Annex 1 of the national law. It is noted that there is an ongoing general debate on whether to (further) restrict or prohibit the reprocessing of SUDs.
- In **Croatia** the outsourcing of reprocessing is limited to EU Member States.
- In **Germany** the reprocessing of SUDs may also be carried out on behalf of a HI by an external service provider if it is ensured that its own MDs are returned to the HI. For the reprocessing of SUDs with particularly high reprocessing requirements (Critical C), certification of the quality management system by an accredited certification body is required according to § 17b of the MPDG. HIs that reprocess or have reprocessed SUDs according to Article 17(3) MDR must notify the CA via the German Medical Devices Information and Database System (Deutsches Medizinprodukte-Informations- und Datenbanksystem, DMIDS) prior to commencing the activity according to § 86 MPDG.
- In the **Netherlands** the reprocessing of a SUD is prohibited if the original SUD has already been reprocessed by another organisation or through another process. Additionally, reprocessing of a SUD is prohibited if:
    a. the SUD has come into contact with one or more of the following tissues: 1. brain, 2. backbone, 3. retina, 4. optic nerve, 5. spinal nerve node, 6. Gasser's ganglion, 7. pituitary gland, 8. hard dura mater;
    b. the SUD has been used for procedures on a patient who has Creutzfeldt-Jakob disease or a variant of it;
    c. the SUD has been used for interventions on a patient with an unexplained neurological condition, which includes at least two of

the following symptoms: 1. progressive dementia, 2. myoclonus, 3. ataxia.

- In **Poland** it is prohibited to make available or continue to use reprocessed SUDs on the territory of the Republic of Poland.
- In **Spain** it is not allowed to transfer SUDs to any other country for reprocessing, i.e. reprocessing may only take place in Spain and any outsourcing or subcontracting is not allowed. Only SUD reprocessors and hospitals can reprocess SUDs (i.e. no other type of HIs). Reprocessing has to be done either in the hospitals' own facilities or is outsourced, in which case a contract with a reprocessor of SUDs is needed. Hospitals are not allowed to reprocess a SUD that has been reprocessed by a MF and have to return this reprocessed device to the MF after use. As for making reprocessed SUDs available or using them further, it is not allowed to sell these products to the public or to other countries. However, hospital and external reprocessors (which are centralised companies reprocessing for hospitals) are not yet allowed to reprocess, as the Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS) has to develop additional regulations for this activity undertaken in hospitals and by external reprocessors.

Notifications according to Article 17(3) and (9)

Table 8 shows that most countries have informed the EC as well as the other Member States according to Article 17(3) and Article 17(9) MDR. However, in some cases, notifications have not yet been made. The EC keeps an up-to-date webpage, based on notifications received from EU and other EEA countries.[9]

Table 8: Notifications in accordance with Article 17(3) and (9) MDR

Country	**Notifications in accordance with Article 17(3)** National provisions introduced pursuant to Article 17(3) MDR (MFs obligations for HIs) and the grounds for introducing them		**Notifications in accordance with Article 17(9)** Restrictions and prohibitions pursuant to Article 17(9) MDR	
	EC has been notified	Other MSs have been notified	EC has been notified	Other MSs have been notified
Belgium	yes	yes	yes	yes
Croatia	yes	no	yes	no

[9] National rules on reprocessing of single-use devices - European Commission (europa.eu)

Country	Notifications in accordance with Article 17(3) National provisions introduced pursuant to Article 17(3) MDR (MFs obligations for HIs) and the grounds for introducing them		Notifications in accordance with Article 17(9) Restrictions and prohibitions pursuant to Article 17(9) MDR	
Germany	yes	yes	no	no
Iceland[1]	no	no	no	no
Ireland	yes	yes	no	no
Netherlands	no	no	no	no
Poland	yes	yes	yes	yes
Spain	yes	no	yes	no
Sweden	yes	yes	yes	yes

Abbreviations: EC = European Commission, MSs = Member State(s)

Note: [1] Iceland is not an EU MS and is therefore not obliged to notify the EC and/or other EU MS.

Source: CA survey (2023)

Transfer of SUDs to other countries

CAs in most of the countries which allow reprocessing (Iceland, Ireland, the Netherlands, Poland) **do not know whether reprocessors** of SUDs according to Article 17(2) MDR (MFs) **transfer reprocessed SUDs from their country to other Member States or non-EU countries**.

Only **Croatia and Sweden** reported that this is **not the case**, while **Spain** indicated that this is **not allowed according to national legislation**. In **Germany**, there is no obligation to report to the Federal Ministry of Health whether or to which countries German reprocessors of SUDs according to Article 17(2) MDR send their reprocessed SUDs.

MFs of other (EU) Member States can make reprocessed SUDs available in their own countries according to the CAs of six countries (Belgium, Germany, Iceland, Netherlands, Spain, Sweden), but not according to the CAs of three countries (Croatia, Ireland, Poland).

Sweden clarified that this is possible but with restrictions: HIs in Sweden can send their used SUDs to reprocessing companies based in other countries and receive back the reprocessed SUDs. **Belgium** explained that national legislation does not explicitly prohibit reprocessing being undertaken outside the EU, so in principle reprocessing could take place in non-EU countries.

Germany clarified that only German reprocessors have to register in the DMIDS database; MFs from other countries can provide reprocessed CE-marked products to Germany.

Vigilance and market surveillance

In **Belgium, Iceland and Ireland,** reprocessed SUDs are included in the annual surveillance activity plans. Poland and Spain have already received reports of serious incidents or Field Safety Corrective Actions (FSCA) involving SUDs. Information from Denmark is not yet available.

3.2.2. National provisions prohibiting the reprocessing of single-use devices

In about **half of the study countries** (9 out of 17: Austria, Cyprus, Estonia, Greece, Hungary, Lithuania, Malta, Norway, Slovakia) **which do not allow reprocessing**, there is **no specific reference to the prohibition of reprocessing SUDs in their national provision(s)**.

National provision(s) regulating prohibition exist for **Bulgaria,** the **Czech Republic, Finland, France, Italy, Latvia, Liechtenstein and Romania**; they are provided in Table 9 below.

Table 9: National provisions regulating the prohibition of reprocessing SUDs

Country	Name of national provision(s) in national language and in English (including link)	Date which the national provisions entered into force
Bulgaria	» **Закон за изменение и допълнение на Закона за медицинските изделия** *(Law for alteration and addition of the law on medical devices)*[1]	Not yet in force
Czech Republic	» **Zákon č. 375/2022 Sb., o zdravotnických prostředcích a diagnostických zdravotnických prostředcích in vitro** *(Act. No. 375/2022 Coll., on medical devices and in vitro diagnostic medical devices)*	22.12.2022
Finland	» **Laki lääkinnällistä laitteista 719/2021 4§** *(Medical Devices Act (719/2021)*	15.7.2021

Country	Name of national provision(s) in national language and in English (including link)	Date which the national provisions entered into force
France	» **Article L5211-3-2 (Code de la Santé Publique)** *Article L5211-3-2 (Public Health Code)* » **Article R6111-21 (Code de la Santé Publique)** *Article R6111-21 (Public Health Code)* » **Instruction n° DGS/RI3/2011/449** *Instruction n° DGS/RI3/2011/449* » **Circulaire n° 669 du 14 avril 1986 relative à l'interdiction de restériliser le matériel médico-chirurgical non réutilisable dit «à usage unique»** *(Circular n°669 (14th April 1986) relating to the prohibition of re-sterilising non-reusable medical/surgical equipment/tools (for single use))* » **Circulaire DGS/SQ 3, DGS/PH 2 – DH/EM 1 n° 51 du 29 décembre 1994 relative à l'utilisation des dispositifs médicaux stériles à usage unique dans les établissements de santé publics et privés** *(Circular DGS/SQ 3, DGS/PH 2 – DH/EM 1 n° 51 (29 December 1994) relating to the use of single-use sterile medical devices in public and private healthcare facilities)*	1986
Italy	» **CIRCOLARE del Ministero della Salute: Rigenerazione e riutilizzo dei dispositivi medici 01/04/2005** *(Ministry of Health Communication: Reprocessing and re-use of medical devices)*	1.4.2005
Latvia	» **Noteikumi par higiēniskā un pretepidēmiskā režīma pamatprasībām ārstniecības iestādē** *(Regulations Regarding the Basic Requirements for a Hygienic and Counter-epidemic Regimen in a Medical Treatment Institution)*	19.2.2016
Liechtenstein	» **Art. 17 EWR-MepV Einmalprodukte und ihre Aufbereitung** *(Art. 17 EWR-MepV Single-use devices and their reprocessing)*	26.5.2021

Country	Name of national provision(s) in national language and in English (including link)	Date which the national provisions entered into force
Romania	» **Ordinul Ministerul Sănătății şi Familiei nr. 185 din 6 martie 2003 pentru aprobarea Normelor tehnice privind asigurarea curăţeniei, dezinfecţiei, efectuarea sterilizării şi păstrarea sterilităţii obiectelor şi materialelor sanitare în unităţile sanitare de stat şi private, cu modificarile si completarile ulterioare** *(Ministry of Health and Family Order No. 185 of March 6, 2003 for the approval of the Technical Norms on ensuring cleaning, disinfection, performing sterilisation and preserving the sterility of sanitary objects and materials in state and private sanitary units, with subsequent amendments)* » **ORDONANTĂ DE URGENTĂ nr. 46 din 9 iunie 2021privind stabilirea cadrului instituţional şi a măsurilor pentru punerea în aplicare a Regulamentului (UE) 2017/745 al Parlamentului European si al Consiliului din 5 aprilie 2017 privind dispozitivele medicale, de modificare a Directivei 2001/83/CE, a Regulamentului (CE) nr. 178/2002 si a Regulamentului (CE) nr. 1.223/2009 si de abrogare a Directivelor 90/385/CEE şi 93/42/CEE ale Consiliului** *(EMERGENCY ORDINANCE No. 46 of 9 June 2021 on establishment of an institutional framework and measures for enforcement of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC)*	2003

[1] Not published.

Source: CA survey (2023)

CAs which do not allow reprocessing reported, that reprocessors of SUDs according to Article 17(2) MDR (MFs) from other EU Member States or non-EU countries can make reprocessed SUDs available in **Lithuania** and **Norway**. In all other 15 countries that do not allow reprocessing (Austria, Bulgaria, Cyprus, the Czech Republic, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Liechtenstein, Malta, Romania, Slovakia) this practice is prohibited.

Reasons why countries do not allow the reprocessing of SUDs

The 17 CAs which indicated that the reprocessing of SUDs is not allowed in their countries provided the **following reasons** (number of mentions in brackets). These can be clustered into three main topics.

Safety concerns

- patient safety concerns (7); additional note: the reprocessor does not know all the materials used in the device (1);
- reprocessed SUDs may increase the biological, chemical and physical hazards associated with the reprocessing procedures compared to reusable medical devices (1);
- absence of guarantees in terms of infectious risk control, but also in terms of technical risk control (the performance of the reprocessed SUD must not be altered), as well as the absence of evidence demonstrating environmental benefits or budget savings (1);
- reusability cannot be fully monitored; the verifiability of reusability is doubtful. It is not entirely clear whose responsibility it is to present clinical evidence of the safety and efficacy of reprocessing (case by case for each SUD) (1);
- several potential hazards have been identified which may eventually lead to a risk for patients on whom a reprocessed SUD is used (1);
- not enough practice and experience in the reprocessing of SUDs (1);
- no entities possess or desire gain the know-how to reprocess SUDs (1).

Regulatory framework

- national legislation prohibiting reprocessing (1);
- lack of control and rules (1);
- reprocessing of SUDs is not explicitly listed as prohibited in the legislation of one CA (1);
- lack of procedures and regulatory frameworks for safe reprocessing since it has not been considered necessary (1);
- several HIs responded to the public consultation stating that they would not be able to fulfil the obligations set out in Article 17(2) and (3) MDR (1).

Reprocessing not foreseen in the intended use of the SUD

- not included in the intended use by the MF (1);
- according to MFs, SUDs are not intended for multiple use, as also confirmed by the conformity assessment. Furthermore, it was argued that

only the MF would have all the necessary information and data on their own product and its design (specifications, performance). For this reason, only the MF was considered to be the right party to evaluate whether the product is suitable for multiple use or not (1);

- it was requested that all devices must be used in accordance with the instructions provided by the MF. Since the safety and compliance of devices is the responsibility of the MF, it was argued that the MFs would not take on responsibility for the reprocessed SUD. (1).

3.3. Practical implementation of Article 17 MDR

The CAs reacted to Article 17 MDR very differently and, as a result, practical implementation by NBs, MFs and HIs hardly exists.

3.3.1. Certification processes of reprocessing single-use devices

Reprocessing SUDs requires the certification of devices and/or activities by a NB.

Only 6 (16%) out of 38 NBs designated under the MDR (and surveyed in the first round of the survey) **indicated that they certify reprocessed SUDs**. These are located in **Croatia**, **Ireland**, the **Netherlands**, **Norway** (even if Norway does not authorise reprocessing of SUDs on its territory), **Slovenia** and **Spain**.

The 32 NBs which indicated that they do **not certify reprocessed SUDs** according to Article 17(2) MDR and/or in compliance with the CS according to Article 17(3) MDR gave the **following reasons for not certifying (yet)**: (number of mentions in brackets)

- not designated (11);
- reprocessed SUDs are not allowed in the country, so the NB did not apply (6);
- no applications from MFs and HIs (4);
- lack of resources (3);
- risk level too high for patients (3);
- no/few customers (2);

- high workload for new notification applications and their related surveillance activities (1);
- not interested (1);
- unclear liability (1);
- doubts on the reprocessing of SUDs, which is not in line with the legal MFs' claimed and declared intended use (1).

In addition, NBs clearly highlighted in the interviews that there is a **lack of client interest/applications** even in countries where reprocessing is allowed. As a result, some NBs do not expect the certification for reprocessing SUDs to be an economically viable activity, also in view of the costs involved in adapting internal processes and applying for such a designation. Furthermore, NBs are **not interested** in taking on this activity as they are **currently understaffed** and face an **extensive workload with their other regular activities**. Against this backdrop, they prioritise other urgent needs in the context of the MDR (certifying new devices), for which they have existing clients.

Designation codes

Regarding the **designation codes** applied to certifying reprocessed SUDs according to Article 17(2) MDR, 5 (out of the 6) NBs indicated the designation code **MDT[10] 2013** (devices which have undergone reprocessing) plus **additional product-specific MDR codes**. In terms of the requirements that enable them to certify compliance with the CS according to Article 17(3) MDR, four NBs repeated the same designation codes (MDT 2013 and product-specific MDR codes), while one NB stated that it would not certify or conduct a conformity assessment in accordance with Article 17(3) MDR. Another NB did not indicate the codes but replied that it had not yet certified reprocessed SUDs. One NB pointed to the lack of national rules for reprocessing which would enable them to certify SUDs according to Article 17(3) MDR.

[10] List of codes for NBs according to the MDR; MDT = devices for which specific technologies or processes are used.

Applications and SUD certifications

Only **two NBs** (Croatia, the Netherlands) replied that they had received **applications for the certification of reprocessed SUDs** according to Article 17(2) MDR **and/or compliance with the CS** according to Article 17(3) MDR. However, **they had not yet issued a certificate for a reprocessed device**. One of the two participating MFs replying to the survey had already submitted applications for certification for reprocessed SUDs to NBs in two countries, while the other had not yet done so.

Even though the tasks for which NBs have been notified are listed in the Single Market Compliance Space (SMCS) database, **the MFs do not seem to be able to identify a suitable NB** (especially for certification of compliance with the CS). This was also confirmed by HIs as none of those that reprocess or plan to reprocess SUDs indicated that they have a certificate of compliance with the CS. Furthermore, no written agreement with a NB responsible for the certification of compliance with the CS has been concluded yet. It was estimated by one MF that it might take 13–18 months to obtain a new EC certificate (from the written agreement being signed to its issuance) from the NB for product certificates or for quality management system (QMS) certificates only under the MDR.

3.3.2. Reprocessing of single-use devices

Reprocessing by manufacturers

A very **low number of MFs reprocessing SUDs** were identified for the **European market** (estimation: only 2 to 5 MFs based in the EU). Two companies, both SMEs located in Germany, were identified as being active in the reprocessing of SUDs: one of the companies acts as a MF of CE-marked products and offers reprocessing as a service complying with the CS, while the other offers reprocessing as a service (CS) only. Both companies deliver **products to the German market**. One of the two companies also makes the reprocessed SUDs available in Belgium, Ireland, the Netherlands, other European countries (non-EU) and in third countries.

The US Association of Medical Device Reprocessors (AMDR) indicated that four companies based in the US would be interested in serving the European market. Conversely, one US-based company reportedly withdrew from the European market because they considered the regulatory framework to be too fragmented,

even though they had previously operated in Belgium and the Netherlands (as well as in the UK).

Health institutions that reprocess or plan to reprocess SUDs

Only **9 HIs** out of the 19 valid replies to the survey indicated that **they reprocess or plan to reprocess and/or reuse SUDs** according to Article 17(2) MDR and/or according to Article 17(3) MDR, with four currently reprocessing SUDs and five planning to do so. All of the HIs are located in countries where reprocessing is allowed according to Article 17(2) MDR and/or according to Article 17(3) MDR, namely Belgium, Croatia, Germany, the Netherlands and Sweden. Eight HIs indicated that they knew about national provisions for reprocessing SUDs, Croatia being the exception. Moreover, 3 out of 9 HIs reported restrictions or prohibitions on the reprocessing of SUDs. One HI which is currently reprocessing SUDs indicated that there are no current restrictions that they are aware of regarding reprocessing SUDs. Three HIs that are planning to reprocess SUDs noted that they aim to (additionally) outsource reprocessing to external reprocessors.

HIs participating in the survey which reprocess or plan to reprocess SUDs considered **cost savings** (89%), **environmental benefits** (56%) and **special circumstances** (such as the pandemic or shortages) (67%) as the **main drivers behind the reprocessing** of SUDs in their institutions. Moreover, four HIs reported that reprocessing was already established in their institutions; hence they continued to do it under the MDR. The interviewed HIs had mixed opinions regarding to the extent to which SUD reprocessing contributes to these benefits.

Ten of the 19 HIs which replied to the survey indicated that they **currently do not reprocess SUDs and are not planning to do so** in the future. They provided the following reasons for their decision not to become involved in the reprocessing of SUDs (number of mentions in brackets):

- lack of resources regarding knowhow, structure and materials of SUDs (3);
- perceived lack of patient safety (2);
- lack of purpose or interest in reprocessing SUDs (2);
- currently not possible for the disposable product to retain its properties (1);
- high requirements for evidence of effectiveness / intended use/validation (1).

Nonetheless, it was also reported in the interviews that **knowledge and understanding of the national provisions or EU legislation on reprocessing is generally limited among HIs**.

SUDs to be reprocessed (types, risk classes and quantities)

The two SME MFs reported that they **reprocess cardiovascular SUDs** (i.e. diagnostic electrophysiology (EP) catheters, ultrasound catheters, mapping catheters, EP cables, and ablation catheters). **One of the two MFs** also reprocesses SUDs for **general surgery** as well as for **laparoscopic and non-invasive interventions**. While one company only reprocesses Class III cardiovascular devices (50% of the company's product portfolio), the other company offers reprocessed SUDs in almost all risk classes (Class I, Class Is, Class IIa, Class IIb, Class III).

HIs indicated that a **broad range of SUDs** from all risk classes (Class I, Class IIa, Class IIb, Class III) are **being reprocessed**. Regarding the types of devices being reprocessed, five HIs reprocess or plan to reprocess **cardiovascular devices**, four **arthroscopic/orthopedic devices**, three **laparoscopic** devices and three **devices for general surgery**. Non-invasive devices, such as scissor tips, are planned to be or are currently being reprocessed by two HIs.

According to one MF, any reprocessed SUD for which technical and hygienic safety has been fully demonstrated and validated is considered safe to be reprocessed. Scientific evidence must demonstrate for each product whether or not a SUD can be reprocessed safely. It depends on the specific structure of the product and the availability of a reprocessing method for which it can be proven that the reprocessed SUDs are fully hygienic and technically safe. According to this MF, a blanket list of product groups suitable for reprocessing cannot be sufficiently justified from a scientific standpoint.

CAs from **Belgium**, **Croatia**, the **Netherlands**, **Poland** and **Spain** indicated that they **do not know / have any information on which types of SUDs are reprocessed in their country**.

Belgium and Spain clarified that national rules provide some restrictions on which SUDs can be reprocessed and that for some types of SUDs reprocessing is not allowed: in Spain these are class I (no NB), custom-made and in-house SUDs; and in Belgium SUDs with non-removable batteries or where data cannot be cleared, SUDs emitting ionising radiation or implantable SUDs.

CAs from **Germany, Iceland, Ireland** and **Sweden** provided **information on types of SUDs reprocessed** in their country (number of mentions in brackets):

- cardiovascular (5); subtype: intravascular catheters (1);
- arthroscopic/orthopedic (3);
- laparoscopic (3);
- general surgery (2);
- non-invasive (2);
- other (2).

Patient information

Two HIs from Belgium and the Netherlands reportedly **inform their patients** about the use of reprocessed SUDs in their health care provision. The Dutch HI provides individual information to the patient, while the HI from Belgium informs patients on its website. Five HIs (four of them planning to reprocess SUDs and one currently reprocessing SUDs) indicated that they do not yet provide information to patients.

3.3.3. Reusing of single-use devices

Four out of 19 HIs (21%) which completed the survey indicated that they **reprocess/plan to reprocess and reuse purchased reprocessed SUDs**.

All four HIs indicated awareness of the existence of **national provisions for reusing reprocessed SUDs** but none of them explicitly stated the provision. HIs usually have a long track record in reprocessing/reusing SUDs. In the interviews, one HI stated that since the MDR came into force, it continues reprocessing EP catheters (simultaneously seeking an NB to certify compliance in accordance with the CS), while a second HI stopped reprocessing itself and only reuses reprocessed EP catheters bought from an external MF. Both interviewed HIs had good knowledge of the national provisions and the EU legal framework, having studied them extensively in order to determine how to proceed with certification according to the CS.

All HIs reused **cardiovascular devices**, predominantly different types of catheters. Two HIs also indicated that they reuse arthroscopic/orthopedic devices

and devices for general surgery as well as laparoscopic and non-invasive devices.

Three out of the four HIs surveyed indicated that they reuse purchased reprocessed SUDs for **economic reasons**. Moreover, special circumstances, such as shortages or the COVID-19 pandemic, resulted in two of the interviewed HIs deciding to reuse SUDs. Other reasons given were that reusing reprocessed SUDs had already been established in the institutions (indicated by two HIs).One HI indicated that they always used to reprocess but now are able to do so under a more certain legal framework. The two interviewed HIs indicated that the decision to reuse reprocessed EP catheters was primarily based on the benefits for patients' treatment as doctors find the tip of the catheters to be softened through reprocessing, which allows for better handling during the medical procedures compared to new single-use catheters. Reusing reprocessed EP catheters is considered to be relatively low risk, also given the long track record of both HIs in reprocessing/reusing this type of SUD.

Among the remaining HIs, views on the reasons for reprocessing/reusing SUDs diverged. For the HIs not reprocessing/reusing SUDs or not planning to do so, the main reasons for their reluctance are that they consider the potential benefits to be limited, they lack specific experience in this area and/or they have concerns about product safety for patients.

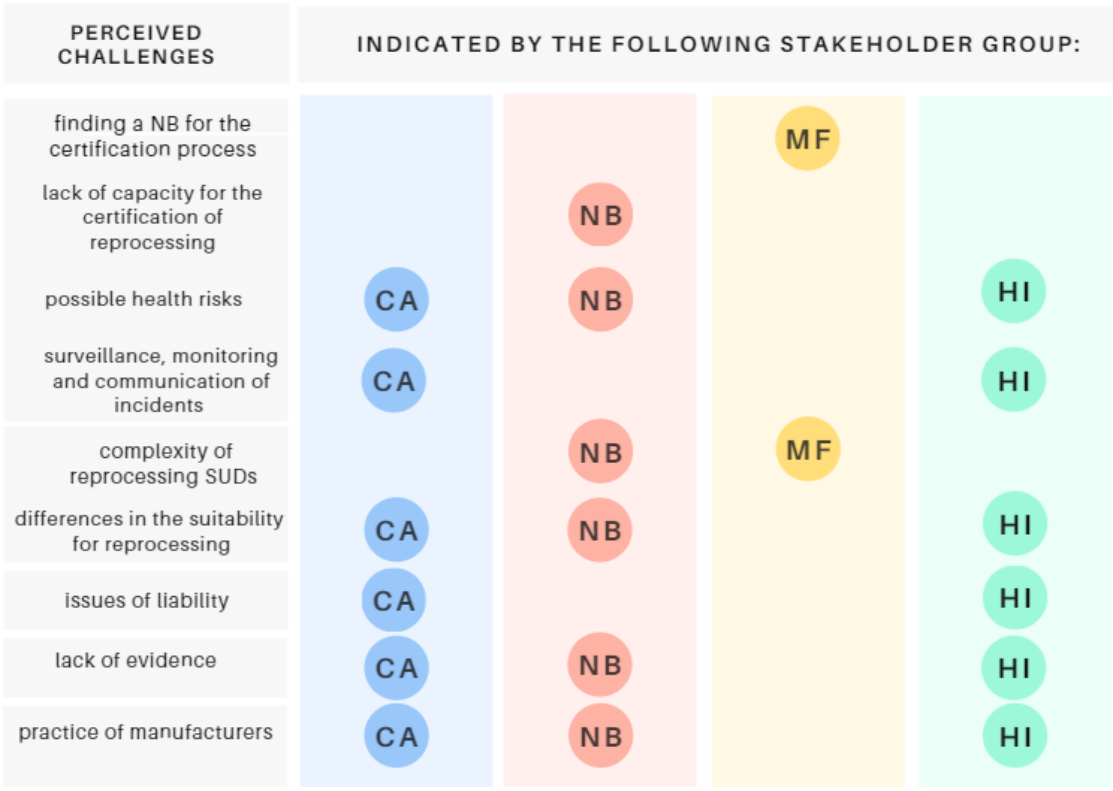
3.4. Challenges and opportunities

During the consultation activities, stakeholders were asked to indicate potential challenges and opportunities which they experience regarding the reprocessing of SUDs. This section presents the main obstacles and perceived opportunities of reprocessing.

3.4.1. Perceived challenges for reprocessing SUDs

All stakeholder groups indicated the following general challenges for reprocessing SUDs (Figure 2).

Figure 2: General challenges for reprocessing SUDs as indicated by the stakeholders



Abbreviations: NB = notified body, CA = competent authority, MF = manufacturer, HI = health institution.

Source: CA, NB, MF, HI surveys (2023)

A major challenge indicated by CAs, NBs and HIs is **possible health risks** for patients through reprocessed SUDs. Nevertheless, reports on evidence of health risks provided by the respondents differ. On the one hand, none of the HIs interviewed could provide any empirical evidence of incidents from their own clinical experience with reprocessing. On the other hand, two HIs that currently reprocess/reuse EP catheters, having engaged in this activity for more than two decades, stated that clinical practice suggests that the use of reprocessed EP catheters is safe and problems scarce. Indeed, evidence derived from the literature review suggests that reprocessing SUDs can be considered safe when following certain procedures. For example, a Swedish report found no significant differences regarding the safety of new and reprocessed SUDs when reprocessed under certain circumstances [5]. Possible health risks come from insufficient testing of devices, not following a strict protocol or when reprocessing highly complex devices [9].

The **surveillance, monitoring and communication of incidents caused by reprocessed SUDs** is another challenge experienced by stakeholders. CAs indicated that they only have limited capacities for surveillance and monitoring activities. A feasibility report from Denmark investigated surveillance and traceability aspects of reusing reprocessed SUDs. Denmark registers each procedure performed on a patient, but not the equipment used in this procedure, meaning that there is no link between patients and devices used during a procedure. As a result, there is no way to assess the safety performance of reprocessed SUDs in case of incidents. It was reported in an interview that even if an appropriate surveillance system were set up, it would take some years to gather enough data to establish causality; this was also the conclusion of the Danish report on this subject [19]. The reported problem also refers to the **issue of liability**, which was mentioned as another challenge by two stakeholder groups.

The main challenge for MFs is **finding an NB for the certification process**. MFs reported on the difficulty of obtaining certification for compliance with the CS due to the lack of NBs that can certify for this purpose. At the same time, NBs reported a **lack of capacity for the certification of reprocessing**. Consequently, this remains the largest obstacle to the implementation of Article 17 MDR according to MFs.

The **complexity of reprocessing SUDs** was considered an obstacle by both MFs and NBs. MFs argued that the complexity of reprocessing strongly depends on the type of SUD reprocessed. While the CS may be easier to apply for the reprocessing of single-use low risk devices than for Class III SUDs, the original product specifications cannot be guaranteed by the reprocessors, as complete technical documentation cannot be provided and/or original product requirements cannot be verified.

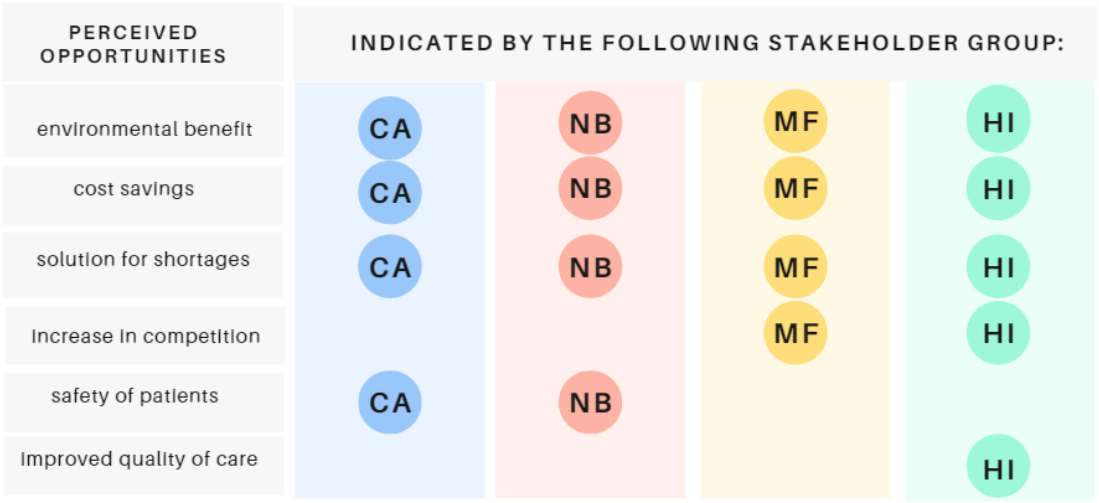
While CAs perceive **differences in the suitability of devices for reprocessing as a major challenge**, only a minority of HIs who reprocess or plan to reprocess SUDs consider this aspect problematic. However, reports indicate that certain SUDs might be more prone to changes in properties or degradation of device materials when reprocessed [10, 13]. Studies found that some devices – specifically in lower risk classes – are suitable for reprocessing [4], although others may be less suitable. Thus, stakeholders also emphasised the need for more evidence and comparative data to validate the suitability of reprocessing SUDs.

Other perceived challenges indicated by stakeholders were ethical considerations, the practice of MFs (for instance, regarding the labelling of SUDs), lack of competence and staff for certifying reprocessed SUDs, the uncertainty of the legal situation in Member States, general doubts about the concept of reprocessing SUDs, lack of experience in certifying reprocessed devices and the lack of potential customers on the market.

3.4.2. Perceived opportunities for reprocessing SUDs

All stakeholder groups indicated **potential opportunities** for the reprocessing of SUDs. An overview of the most common ones mentioned is presented in Figure 3.

Figure 3: Opportunities for reprocessing SUDs indicated by the stakeholders



Abbreviations: NB = notified body, CA = competent authority, MF = manufacturer, HI = health institution.

Source: CA, NB, MF, HI surveys (2023)

All stakeholder groups consider **cost savings, environmental benefits** and a **mitigation measure for shortages** as being beneficial. This result is consistent with findings in the literature as cost savings and environmental benefits are the most commonly cited benefits of reprocessing SUDs. For instance, studies found a positive environmental impact for reprocessing SUDs [6, 7]. One study also found cost savings through reprocessing SUDs of around 50% in comparison to buying new SUDs [4]. Moreover, MFs and HIs see a benefit in reprocessing SUDs through an **increase in competition**. However, only a minority of CAs and NBs perceive this to be an important factor.

Several HIs pointed out that an **enhanced quality of care** for patients is a benefit of reprocessing SUDs, specifically with reference to EP catheters. For instance, as noted above, one HI explained that reprocessed EP catheters could have reduced stiffness, enabling cardiologists to perform treatments more effectively in patients with challenging anatomies.

While various opportunities were identified by all stakeholder groups, uncertainties persist regarding certain aspects of reprocessing. Concerning cost savings, some CAs pointed out that the **extent of achievable cost savings depends on various factors**. For instance, certain hospitals are increasingly opting to pool resources to share costs. In general, NBs and CAs stressed the need to **balance opportunities against potential risks to patient health**, emphasising that patient safety should be the overarching goal in implementing Article 17 MDR.

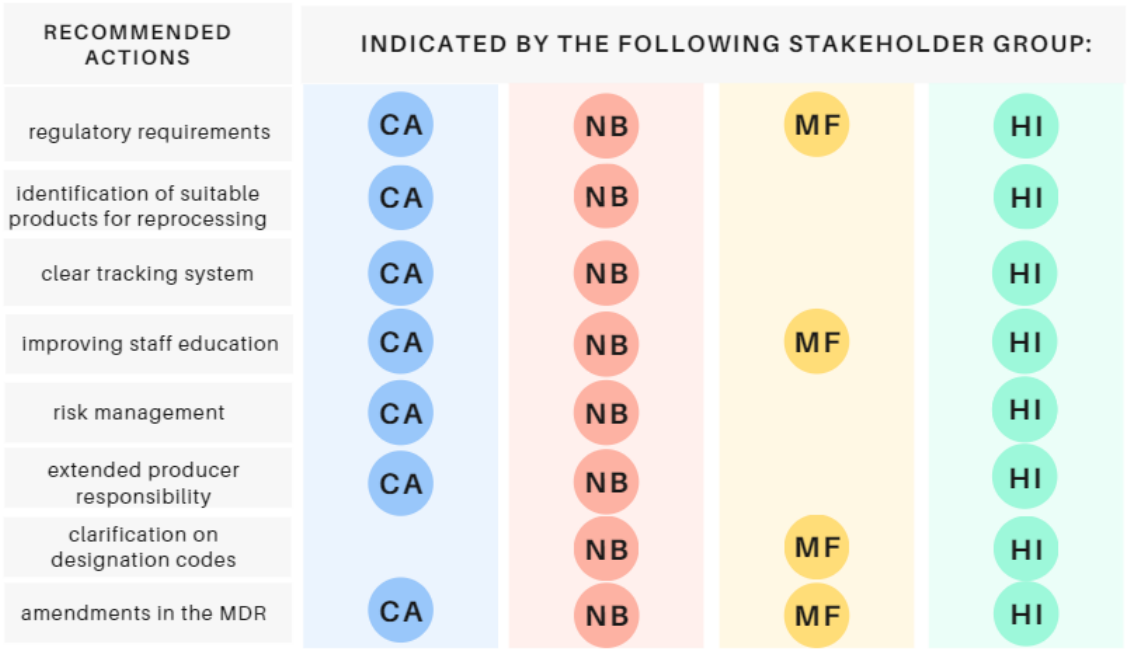
3.5. Stakeholder-recommended actions and ongoing discussions

In the consultation activities, stakeholders recommended actions that could be taken to improve the implementation of Article 17 MDR on the European market. Moreover, they indicated whether discussions on changing the current state of the implementation of Article 17 MDR are ongoing in the Member States or institutions. The key results of stakeholder-recommended actions and ongoing discussions are summarised in the following subsections.

3.5.1. Stakeholder-recommended actions

All stakeholder groups indicated potential actions that could be implemented to improve the situation for reprocessing SUDs in Europe. Recommendations from the various categories of stakeholders are presented in Figure 4.

Figure 4: Potential actions and recommendations indicated by the stakeholders



Abbreviations: NB = notified body, CA = competent authority, MF = manufacturer, HI = health institution.

Source: CA, NB, MF, HI surveys (2023)

Stakeholders recommended actions which were indicated by the majority of stakeholders were **strengthening regulatory requirements** and establishing a **clear tracking system**. CAs, NBs and HIs also recommended **improving staff education** and **strengthening risk management** for reprocessed SUDs.

Furthermore, all stakeholder groups agreed on the **necessity for more evidence on reprocessing and its economic and environmental impacts**. They advocated more scientific studies on safety, more surveillance of reprocessing, establishing expert groups or forums for specific product groups and more empirical/qualitative evidence based on the insights of medical professionals who have engaged in the reprocessing of SUDs. Two CAs shared updates on ongoing studies in their country. An Irish CA is currently evaluating its policy on reprocessing and a review of the literature on its impacts; France is currently preparing proposals which may allow reprocessing for a two-year trial period during which it is hoped to gather relevant evidence.

In terms of **strengthening regulatory requirements**, stakeholders emphasised in particular the need for suitable qualifications for operators conducting the reprocessing. For instance, one NB proposed adding preconditions for the reprocessing company in Article 52 MDR to ensure that reprocessors have the technical ability to reprocess SUDs. Stakeholders also proposed establishing

guidelines, including a **step-by-step manual for the implementation of the MDR and the CS**. Furthermore, HIs recommended **strengthening the support from regulatory authorities** at national or EU level, which might help to address the lack of NBs willing to certify according to the CS. Moreover, **task forces or working groups at EU level could be established in order to exchange current information and best practices** with those stakeholders which have a long-standing history in reprocessing, such as Germany.

Furthermore, the **identification of suitable products for reprocessing** was considered a potential action by all stakeholder groups except for MFs. While CAs and NBs were in favour of both positive or negative **EU-wide lists**, MFs opposed the idea, suggesting that a single list could not be fully justified from a scientific perspective and would be difficult to establish. Both of the MFs perceive **changes in Article 17 MDR** to be as a potential action due to the subsidiary approach in the implementation of Article 17 MDR where the decision on whether to allow the reprocessing of SUDs is the responsibility of individual Member States. Moreover, the MFs highlighted the need for a transition period until 2027 for reprocessing according to Article 17 MDR as was the case for MFs of medical devices in the MDR. One industry association reported that, as the MDR currently stands, there is a strong incentive for MFs to label products as 'single-use' rather than reusable. This actively hinders the aim of achieving a circular economy in the medical devices sector. According to this association, there are variations in the extent to which products are reusable in practice, and this should be determined on a product-by-product basis by NBs as an independent external party.

3.5.2. Ongoing discussions

Competent authorities: multiple CAs indicated that there are ongoing discussions on whether to allow the reprocessing of SUDs in the future, for instance in the Czech Republic and Latvia. In the Czech Republic, the Ministry of Health is currently conducting a survey evaluating whether the reprocessing of SUDs might have support across the relevant stakeholders.

Other countries, such as Bulgaria, Finland, France, Italy and Slovakia, reported that the reprocessing of SUDs might be allowed under certain circumstances (e.g. shortages, the economic situation in hospitals, health crises) in the future. However, Austria, Cyprus, Estonia, France, Liechtenstein, Lithuania, Malta, Norway and Romania indicated that there are no ongoing discussions on potentially allowing reprocessing. In Greece and Hungary, the CAs reported they did not know whether discussions are ongoing. Further information on ongoing

discussions was provided in the follow-up interviews with French and Danish CAs where reprocessing is not currently allowed in their countries.

The CA from France reported that a draft proposal is under preparation which may possibly allow the reprocessing of SUDs during a trial period of two years; a final decision from the French Parliament is expected after this. It is hoped that the two-year trial period will allow some data to be collected on the safety of reprocessing as well as on the economic and environmental benefits.

Moreover, the CAs were asked whether there are currently ongoing discussions and planning activities with the aim of addressing identified challenges and opportunities. Six CAs indicated that such discussions are ongoing. In Iceland and Ireland, feasibility/evaluation studies on reprocessing SUDs are currently being conducted. The Irish CA specified that a survey of HIs is being conducted to evaluate the national policy decision regarding the reprocessing of SUDs; additionally, a review of the literature to determine the safety of reprocessing SUDs was commissioned by the CA. The German and Irish CAs reported that legal amendments are planned for their countries. Other current discussions concern challenges in the certification process as well as evidence generation and provision.

Notified bodies: three NBs reported ongoing discussions addressing the challenges identified regarding reprocessing. In general, three NBs declared their confusion relating to Article 17 MDR, in particular regarding the implementation and practicability of the CS as well as on issues of liability. One NB noted that for higher risk classes (e.g. Class III devices), the original product specifications cannot be guaranteed by the reprocessor, for instance due to a lack of technical data or a lack of competency regarding the product information. Hence, NBs wish for further clarification on these points.

Manufacturers: one MF reported a need to address the following points in ongoing discussions:

- the availability of NBs;
- harmonising/ensuring uniform implementation of Article 17 MDR;
- avoiding negative lists;
- transfer/sourcing of used devices;
- only used SUD products from the EU can be reprocessed in the EU. (according to Article 17(6) MDR).

Health institutions: the majority of HIs declared that there are no discussions ongoing at the moment. The exceptions were two HIs from Belgium and Sweden, which are currently establishing internal systems to regulate liability issues or to send a request for information to NBs about the certification for reprocessing SUDs.

4. Conclusions

Great interest of stakeholders in the topic – except for HIs

CAs, NBs and MFs that reprocess SUDs **showed great interest in participating in the survey** and the follow-up interviews. This was also reflected in the high response rate achieved for these three key stakeholder groups. Only the HIs did not participate in the study to the extent expected. Only a few responses were submitted from the large number of HIs in the 30 countries covered by the study, despite extensive efforts of the study team to improve the response rate is certainly one limitation of the study.

Fragmented implementation of Article 17 MDR

The review on how the provisions laid down in Article 17 MDR have been implemented by the study countries **shows a very diverse picture** as each country can decide for itself whether to allow the reprocessing of SUDs.

More than half of the participating countries (17 out of 30 countries: Austria, Bulgaria, Cyprus, the Czech Republic, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Liechtenstein, Lithuania, Malta, Norway, Romania, Slovakia) **do not allow reprocessing** according to Article 17(2) MDR and/or compliance with the CS according to Article 17(3) MDR. Eight countries (Bulgaria, the Czech Republic, Finland, France, Italy, Latvia, Liechtenstein, Romania) have included a specific prohibition in their legislation, while in the other countries there is no specific reference to prohibition in their national provisions.

One third of the countries (10 out of 30 countries: Belgium, Croatia, Denmark, Germany, Iceland, Ireland, the Netherlands, Poland, Spain, Sweden) **allow the reprocessing of SUDs.** Authorisation is implemented in national provisions regulating the reprocessing and further use of SUDs in accordance with Article 17(1) MDR in nine countries. At the time of the second survey Denmark (the tenth country where reprocessing will become allowed) was still working on national provisions. Article 17 MDR allows for further national options, restrictions, and prohibitions (e.g. if the country applies Article 17(2) or (3) MDR), which adds further complexity to understanding national implementation of the Article.

Four countries (Germany, Iceland, Ireland, the Netherlands) have provided further relevant specifications or further documents (e.g. guidelines or recommendations) relating to the reprocessing of SUDs.

Only **3 out of 30 countries** (Luxembourg, Portugal, Slovenia) **have not made a decision yet**, due to the divergent opinions of stakeholders and bureaucratic issues.

Information gap on the national provisions of EU Member States that permit the reprocessing of SUDs

According to Article 17(9) MDR, EU Member States that permit reprocessing shall notify the Commission and the other Member States of those national provisions. The Commission publishes the information on its website. However, the 2023 survey showed that in some cases notifications had not been made by Member States and that the website is not up to date (the last update was in April 2022). This makes it very difficult for MFs, NBs or HIs to have an overview of the current regulatory framework in different countries.

Hardly any evidence-based decision making for allowing/not allowing the reprocessing of SUDs

Preliminary studies, national political debates, historical authorisations and public consultations were the reasons countries gave for allowing the reprocessing of SUDs. In contrast, safety concerns, legal requirements and the intended use of (single-use) devices were reasons why some countries do not allow the reprocessing of SUDs. As there are very few studies on the subject, the decisions do not seem to be evidence-based. **This underlines the necessity for further evidence and facts.**

Ethical considerations such as patient consent and equal access to treatment are also criteria to be considered by policy makers.

Environmental impact and cost savings given as main reasons for reprocessing SUDs

All stakeholder groups believe that reprocessing SUDs leads to cost savings and environmental benefits. CAs and HIs indicated that reprocessing can provide a solution to shortages, while MFs and HIs considered that reprocessing SUDs may result in an increase in competition and, therefore, improved availability/affordability. However, some CAs pointed out that the extent of achievable savings depends on various factors and that hidden costs should not be disregarded.

Fragmentation and complexity in implementation leads to a potential knowledge gap regarding the legal context of reprocessing

The current regulatory framework seems to be challenging with unclear policies and varying interpretations, leading to potential confusion and dissatisfaction among stakeholders. HIs and MFs in particular reported a lack of interest in reprocessing due to the diversity and complexity in the national implementations of the regulations in various Member States, in other words, the lack of a common EU-wide approach.

Certification as a bottleneck – only a few NBs certify reprocessed SUDs or reprocessing SUDs, but no certificate under MDR issued so far

Six out of 38 NBs designated under the MDR surveyed in the first round (16%; located in Croatia, Ireland, the Netherlands, Norway, Slovenia, Spain) responded that they certify reprocessed SUDs or the reprocessing of SUDs. Only two NBs (Croatia, the Netherlands) replied that they have received applications for the certification of reprocessed SUDs. However, they have not issued a certificate for a reprocessed device yet.

Even though the tasks for which NBs have been designated are listed in the Single Market Compliance Space (SMCS) database, **the MFs (and HIs) do not seem to be able to identify a suitable NB** (especially for the certification of compliance with the CS). According to the MFs this remains the biggest obstacle to the implementation of Article 17 MDR as they depend on certification by NBs to place their products on the market. MFs and HIs reported an inability to obtain certification for compliance with the CS due to the lack of NBs that can certify for this purpose. According to NB representatives, there are no NBs qualified to certify reprocessing under Article 17(4) MDR to date. In addition, according to NBs, the **designation codes** for certifying reprocessed SUDs remain **unclear** to many NBs, which leads to a lack of interest in applying for designation.

At the same time, NBs reported a **lack of capacity for the certification of reprocessing** as they are currently understaffed and face an extensive workload with their other regular activities. NBs also expressed their confusion particularly regarding two aspects of **Article 17 MDR**, namely liability and the implementation of CS. NBs would like clarification on these points.

A small market – a very low number of MFs reprocessing SUDs on the European market

The survey has shown that there are currently very few (less than five; only two identified) reprocessors of SUDs operating on the European market. The lack of

clients and applications, even in countries where reprocessing is allowed, are further reasons for the low interest of NBs to actively operate in this field. US-based companies that are interested in serving the EU market reported that the national regulations in EU Member States are too fragmented to operate effectively.

Stakeholder perspectives on reprocessing SUDs differ

In general, both NBs and CAs indicated that opportunities should be weighed against the potential risks to patient safety. The **safety of patients** should be the overall goal in the implementation of Article 17 MDR in line with its objectives.

Nevertheless, reports on evidence of health risks indicated by the respondents or found in the literature come to different conclusions. This makes it particularly difficult for stakeholders to make an informed judgement on the health risks of using reprocessed SUDs. As indicated in the literature, policy makers tend to prefer single-use disposables for their perceived safety benefits, which reflects the implementation of Article 17 MDR in the countries surveyed (reprocessed SUDs are not allowed in the majority of the countries).

For the HIs not reprocessing/reusing SUDs or not planning to do so, the main reason for their reluctance is that they consider the potential benefits to be comparatively limited; they lack specific experience in this area and/or have concerns about product safety for their patients. Other HIs indicated that an improvement in the quality of care for patients is one benefit of reprocessing SUDs, specifically with reference to electrophysiology catheters (EP), although this view was not shared by all of the healthcare professionals interviewed for the study.

Knowledge and understanding of the national provisions or EU legislation on reprocessing is generally limited among HIs

The survey was sent for dissemination to 15 national associations of HIs in six Member States where the reprocessing of SUDs is allowed. Only 19 valid replies were received from HIs. No information on the total number of HIs using reprocessed SUDs in Europe is available; hence the exact response rate could not be determined. More than half of the HIs indicated that they currently do not reprocess SUDs and are not planning to do so in the future.

On the other hand, it was reported that the (few) HIs that do reprocess SUDs usually have a long-track record in reprocessing/reusing SUDs. They have good knowledge of national provisions and the EU legal framework, having studied them extensively in order to determine how to proceed with certification according

to the CS. However, it can be assumed that many more HIs are reprocessing SUDs in practice, presumably with only a few being aware of the legal situation, as literature and anecdotal knowledge suggests.

Reprocessing of SUDs – a complex matter?

The complexity of reprocessing SUDs was considered an obstacle by MFs and NBs. MFs argued that the complexity of reprocessing is strongly dependent on the type of SUD reprocessed. While the CS may be easier to apply for the reprocessing of single-use low risk devices than for Class III SUDs, the original product specifications cannot be guaranteed by the reprocessors, as the complete technical documentation cannot be provided and/or original product requirements cannot be verified. It is not entirely clear whose responsibility it is to present clinical evidence for the safety and efficacy of reprocessing (case-by-case for each SUD). Doubts were raised that the reprocessor knows about all of the materials in the device and that changes to the devices result from the reprocessing.

Cardiovascular, arthroscopic/orthopedic, laparoscopic and SUDs for general surgery were reported as being reprocessed by MFs, CAs and HIs; cardiovascular SUDs form the majority of reprocessed devices.

According to one MF, any reprocessed SUD for which technical and hygienic safety has been fully demonstrated and validated is considered safe to be reprocessed. Scientific evidence must demonstrate whether or not each type of SUD can be reprocessed safely. This depends on the specific structure of the product and the existence of a reprocessing method for which it can be proven that the reprocessed SUDs are fully hygienic and technically safe and efficient. While CAs and NBs were in favour of either a positive or negative list, MFs opposed the idea of EU-wide lists. They indicated that a single list cannot be fully justified from a scientific perspective and would be difficult to set up and maintain.

Labelling products as single use as a marketing strategy?

Some HIs argued that MFs could make SUDs reusable but refrain from doing so for economic reasons. According to MFs, SUDs are not intended for multiple use, as also confirmed by the conformity assessment, and only the MF was in a position to evaluate whether the product is suitable for multiple use or not. Certain NBs voiced concerns that if MFs' advice or recommendations for the safe use of devices marketed for single use and not for reuse were disregarded, reprocessing would not be in line with the MFs' claimed and declared intended use. According to the MFs, there are variations in the extent to which products are reusable in

practice, and this should be determined on a product-by-product basis by NBs as an independent external party. The strong incentive for MFs to label products as ‘single use’ rather than reusable actively impedes the aspiration to achieve a circular economy in the medical devices sector.

A robust surveillance and tracking system is needed for reprocessed SUDs

The surveillance, monitoring and communication of incidents involving reprocessed SUDs is another challenge experienced by stakeholders. CAs indicated only limited capacities for surveillance and monitoring activities on reprocessing.

Potential actions and recommendations require involving all stakeholders

The most common recommended actions were strengthening regulatory requirements and introducing a clear tracking system. CAs, NBs and HIs also recommended improving staff education and strengthening risk management for reprocessed SUDs. All stakeholder groups agreed on the need for more evidence on reprocessed SUDs and their economic and environmental impacts.

5. Recommendations

Table 10 provides a set of recommendations for removing obstacles in the implementation of Article 17 MDR which were developed and clustered in five topics by the study team based on the evidence collected in the course of the study, including insights from the four key stakeholders in the surveys and interviews.

Table 10: Recommendations for improving the implementation of Article 17 MDR

Recommendation (R)	Description	Targeting
1 GENERAL RECOMMENDATIONS		
R1: Promote evidence (generation)	As there seem to be very few studies on the subject, the decisions why reprocessing is or is not allowed are not evidence based. This underlines the necessity for further evidence and facts, for example, on safety and surveillance, economic and environmental impacts and ethical questions on the reprocessing of SUDs taking into account the differences between reprocessing by HIs or MFs. Funding of targeted research programmes could provide an incentive to increase the production of new evidence and thus create a better basis for evidence-based decision making in this field.	CAs, EC, MFs, HIs, research institutes
R2: Support clarity and transparency on national provisions	The implementation of Article 17 MDR is very fragmented in the study countries, which makes clarity and transparency on national provisions crucial. This includes regularly monitoring, updating and expanding the information on national provisions on the reprocessing of SUDs in EU Member States on the EC website.	CAs, EC
R3: Communicate and support capacity building	The provision of general information material and/or information campaigns as well as training programmes addressing the different stakeholder groups would increase awareness and knowledge of the regulatory framework and other aspects related to the reprocessing of SUDs in and outside Europe.	CAs, EC

Recommendation (R)	Description	Targeting
R4: Establish task forces or working groups	The establishment of task forces or working groups at European level could help to exchange information (also on best practices) and to discuss and clarify open questions regarding the regulatory and practical implementation of reprocessing SUDs among all stakeholders involved. This can lead to the development of guidance documents and to more cooperation and harmonisation among Member States (MSs).	EC, CAs
R5: Involve stakeholders	Key stakeholders should be involved in the discussion of reprocessing-related issues and in the development of targeted actions.	EC, CAs
2 LEGAL FRAMEWORK AND GUIDANCE DOCUMENTS		
R6: Clarify terms and concept to ensure common understanding	Despite the specifications and definitions provided in the MDR, some stakeholders, including NBs and CAs, expressed the need for further clarity. Undertaking activities to increase clarity could be built into several of the recommended measures, in particular the development of a guidance document (see R7), and as part of capacity building activities.	EC, CAs and NBs
R7: Develop guidance documents	All consulted stakeholder groups expressed a need for more clarity, in particular when it comes to implementation issues. Guidance documents (e.g. Q&As) could make an important contribution to responding to this need. In the production of these guidance document, lessons learnt from this study on the need for further information as well as further stakeholder consultation would be an asset. Some of the guidance documents might be designed as a manual; for instance, in countries where reprocessing is allowed, they could inform MFs and HIs on the necessary steps to consider taking when moving forward with the reprocessing of SUDs.	EC

Recommendation (R)	Description	Targeting
R8: Monitor the implementation of Article 17 MDR	The study covers the status of the implementation of Article 17 MDR as of 31 December 2023. Developments and changes are expected, for example in countries in which discussions are ongoing on potentially permitting the reprocessing of SUDs. Given that the MDR is rather recent, lessons learnt from the implementation of Article 17 MDR are expected. It would be of value for other stakeholders and countries to learn about experiences in countries where the reprocessing of SUDs is permitted. It is recommended that the EC, supported by CAs, puts a process in place to monitor the implementation of Article 17 MDR by taking stock of further developments and ensuring that experience is shared.	EC, CAs
3 CERTIFICATION		
R9: Inform MFs about NBs designated for certifying the reprocessing of SUDs	A major challenge for MFs is to identify a NB which offers the service of certifying reprocessors. Clarification on how to read information already available in the SMCS might suffice.	NBs, EC
R10: Clarifiy concepts and accountability of NBs for certification of compliance with the CS	At the time of the study, no NB is qualified to certify reprocessed SUDs under Article 17(4) MDR. This lack of NBs to offer certification might be attributable to limited clarity on the tasks and responsibilities necessary for certification (including the designation codes, see R11). As part of offering guidance (see R7) and working on ensuring further clarity (see R6), the EC may pay particular attention to some aspects of governance and accountability around certification, such as the tasks and responsibilities of NBs when certifying the reprocessing of SUDs under Article 17 MDR.	EC
R11: Clarify NB designation codes	Among the need of NBs for more clarity around certification processes, uncertainty exists in particular regarding the designation codes for certifying reprocessed SUDs. Thus, recommended guidance provided by the EC should also address this issue.	EC

Recommendation (R)	Description	Targeting
R12: Implement training programmes for NBs	There is a lack of NBs offering certification, attributed, among others, to uncertainty and limited capacity in this new field. Additionally, if NBs start offering this service, they require qualified staff to deal with this new area. Workshops and webinars could strengthen the knowledge of NBs' staff about Article 17 MDR and thus increase the capacity. As an additional benefit, coordinated capacity-building programmes are likely to contribute to a more harmonised approach by the NBs in the certification processes across the EU.	EC, NBs
4 IMPLEMENTATION IN MEMBER STATES		
R13: Take measures to support the implementation of reprocessing SUDs at national levels	Even in the 10 countries where reprocessing is permitted, the reprocessing of SUDs is comparatively limited for various reasons. In addition to action taken by the EC as proposed in the other recommendations, it is vital that Member States take targeted measures (e.g. increase of NBs' capacity, incentives for MFs to offer reprocessing) to support and complement the EC's action. These measures are to be aligned to the country's specific context. Roadmaps outlining national action plans would be supportive.	MSs, CAs and NBs
R14: Implement targeted measures for HIs	It was reported that knowledge and understanding of the national provisions or EU legislation on reprocessing SUDs is generally limited among HIs. Thus, to support and encourage this stakeholder group, they should be addressed specifically by targeted measures (e.g. information campaigns, capacity building measures). Such measures taken by Member States could complement actions by the EC to target this specific group and would benefit from being aligned to EC measures.	MSs, EC

Recommendation (R)	Explanation of recommendation	Targeting
5 PRODUCT-RELATED RECOMMENDATIONS		
R15: Develop recommendations on the suitability of different types of SUDs for reprocessing	Currently, guidance as to which SUDs are suitable for reprocessing is missing in the EU. All stakeholders would benefit from guidance that specifies which types of devices have been assessed as being suitable for reprocessing (a positive list) or a list of which types of devices have been assessed as not being suituable for reprocessing (a negative list). Such a positive or negative list would need to be based on robust evidence as well as practical experience. The development of this positive, or negative, list would be challenging given the limited evidence for the time being. Regular updates of this list would be needed to account for new developments.	EC, CAs, MFs
R16: Use of EUDAMED	The European database on medical devices (EUDAMED) could be used as a central source of information and could even include more data fields for reprocessed SUDs.	EC
R17: Support improved risk management and market surveillance	A robust surveillance and tracking system for reprocessed SUDs is needed; all actions underpinning the establishment of such systems, such as sharing best practices and reporting incidents, should be supported.	CAs, MFs

Source: the contractor

6. References

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, L 117/1 (2017).

[2] Commission implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices L 273/3 (2020).

[3] Costa FS, Pereira MO, Esteves C, Carvalho J. Reprocessing of Single-Use Medical Devices in hospital environment: evolution and future perspectives. Lisbon, 2019. Available from https://ieeexplore.ieee.org/document/8692510 (accessed: 14.02.2023).

[4] de Sousa Martins B, Queiroz e Melo J, Logarinho Monteiro J, Rente G, Teixeira Bastos P. Reprocessing of Single-Use Medical Devices: Clinical and Financial Results. Portuguese Journal of Public Health. 2018;36(3): 150-6.

[5] Socialstyrelsen. Förutsättningar för att reprocessa och återanvända medicintekniska engångsprodukter i Sverige. 2020. Available from https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2020-12-7158.pdf (accessed: 14.02.2023).

[6] Meister JA, Sharp J, Wang Y, Nguyen KA. Assessing Long-Term Medical Remanufacturing Emissions with Life Cycle Analysis. Processes. 2022;11(1): 36-.

[7] Schulte A, Maga D, Thonemann N. Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters. Sustainability. 2021;13(2): 898.

[8] Joint Commission International. Reuse of Single-Use Devices: Understanding Risks and Strategies for Decision-Making for Health Care Organizations 2017. Available from https://www.jointcommissioninternational.org/-/media/jci/jci-documents/offerings/other-resources/white-papers/jci_white_paper_reuse_of_single_use_devices.pdf (accessed: 13.02.2023).

[9] Medicines and Healthcare Products Regulatory Agency. Single-use medical devices: implications and consequences of reuse., 2021. Available from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf (accessed: 14.02.2023).

[10] Renton D, Denk P, Varban O. Reprocessed single-use devices in laparoscopy: assessment of cost, environmental impact, and patient safety. Surgical Endoscopy. 2018;32(10): 4310-3.

[11] Benedettini O. Green Servitization in the Single-Use Medical Device Industry: How Device OEMs Create Supply Chain Circularity through Reprocessing. Sustainability 2022. 2022(14): 12670.

[12] Bayrak T, Soylu S. Reprocessing of single use medical devices: A new proposal for a regulation. Health Policy and Technology. 2021(Volume 10, Issue 3, September 2021): 100553.

[13] Duncker D, Svetlosak M, Guerra F, Nagy K, Vanduynhoven P, Mikhaylov E, et al. Reprocessing of electrophysiology material in EHRA countries: an EHRAYoung EP survey. Europace. 2020;00: 1-7.

[14] Mihanović J, Pogorelić Z, Skitarelić N, Karlo R, Jukić M, Stipančić I. Reuse of single-use surgical equipment. Survey on current practice and attitudes in Croatia. MedJad. 2021;51(2): 109-19.

[15] MacNeill AJ, al. e. Transforming The Medical Device Industry: Road Map To A Circular Economy. HEALTH AFFAIRS. 2020(39, NO. 12 (2020)): 2088–97.

[16] Hennein R, Goddard E, Sherman JD. Stakeholder perspectives on scaling up medical device reprocessing: A qualitative study. PLOS ONE. 2022;17(12): e0279808.

[17] Silva GS, Thiel C. What Would It Mean for Health Care Organizations to Justly Manage Their Waste? AMA J Ethics 2022. 2022(24(10)): E934-43.

[18] Chang CWD, Brenner MJ, Shuman EK, Kokoska MS. Reprocessing Standards for Medical Devices and Equipment in Otolaryngology: Safe Practices for Scopes, Speculums, and Single-Use Devices. Otolaryngol Clin North Am. 2019;52(1): 173-83. Epub 2018/09/29.

[19] Midt. MDR artikel 17: Skal der tillades genbehandling af medicinsk engangsudstyr i Danmark?, 2022.

[20] Health Products Regulatory Authority. Reprocessing of single-use devices. 2017. Available from https://www.hpra.ie/homepage/medical-devices/regulatory-information/medical-devices-regulation/reprocessing-of-single-use-devices (accessed: 14.02.2023).

[21] Kompetenzzentrum Hygiene und Medizinprodukte. Übersicht zum nationalen Medizinprodukterecht. Reutlingen, 2021. Available from https://www.hygiene-medizinprodukte.de/fileadmin/user_upload/dokumente/Aktuelles/2021-07-01_%C3%9Cbersicht_nationales_MP-Recht.pdf (accessed: 14.02.2023).

[22] Johnson + Johnson Medical Device Company. FAQs: Medical Device Reprocessing. 2019. Available from https://www.jnjmedtech.com/sites/default/files/user_uploaded_assets/pdf_assets/2019-04/JJMDC%20RPO%20FAQs.pdf (accessed: 14.02.2023).

[23] Federal Agency for Medicines and Health Products. Coronavirus: circular for care institutions on the (outsourcing of the) manufacture and reprocessing of medical devices and their accessories. 2021. Available from https://www.jnjmedtech.com/sites/default/files/user_uploaded_assets/pdf_assets/2019-04/JJMDC%20RPO%20FAQs.pdf (accessed: 14.02.2023).

[24] US Government Accountability Office. Reprocessed single-use medical devices. FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk. GAO, 2008.

[25] Loftus TJ. A Comparison of the Defect Rate Between Original Equipment Manufacturer and Reprocessed Single-Use Bipolar and Ultrasound Diathermy Devices. Journal of Medical Devices. 2015;9(4).

[26] Crawford TC, Eagle KA. Reuse of catheters and devices labelled for single use: evidence, recommendations and oversight. Heart Asia. 2018;10(2): e011033. Epub 2018/12/18.

[27] World Health Organization. Decommissioning medical devices. Geneva: WHO, 2019. Available from https://apps.who.int/iris/bitstream/handle/10665/330095/9789241517041-eng.pdf?sequence=1&isAllowed=y (accessed: 14.02.2023).

[28] WHO, Pan American Health Organization. Decontamination and Reprocessing of Medical Devices for Health Care Facilities. Geneva: World Health Organization, 2016.

[29] World Health Organization. Decontamination and reprocessing of medical devices for health-care facilities: aide-memoire. WHO, 2022. Available from https://apps.who.int/iris/handle/10665/364587 (accessed: 14.02.2023).

[30] Grantcharov P, Ahmed S, Wac K, Rivas H. Reprocessing and reuse of single-use medical devices: perceptions and concerns of relevant stakeholders toward current practices. JBI Evidence Implementation. 2019;17(1).

[31] European Commission. Outcome of the first public consultation on the reprocessing of medical devices - Synthesis document. 2020. Available from https://health.ec.europa.eu/system/files/2020-09/md_consultation_synthesis_en_0.pdf (accessed: 14.02.2023).

[32] Meissner M, al. e. Evaluating the Waste Prevention Potential of a Multi- versus Single-Use Surgical Stapler. Risk Management and Healthcare Policy 2021. 2021(14): 3911–21.

[33] Kane GM, Bakker CA, Balkenende AR. Towards design strategies for circular medical products. Resources, Conservation and Recycling. 2018(Volume 135, 2018): 38-47.

[34] Rowan NJ, Laffey JG. Challenges and solutions for addressing critical shortage of supply chain for personal and protective equipment (PPE) arising from Coronavirus disease (COVID19) pandemic – Case study from the Republic of Ireland. Science of The Total Environment. 2020;725: 138532.

[35] Prasad V. Competition and Innovation: Evidence from Third-Party Reprocessing in the Medical Device Industry. Duke University, 2020. Available from https://sites.duke.edu/djepapers/files/2020/07/varunprasad-dje.pdf (accessed: 14.02.2023).

[36] Wang D, Wu J. Reprocessing and reuse of single-use medical devices in China: a pilot survey. BMC Public Health. 2019;19(1): 461.

[37] Heidbuchel H. Reprocessing of catheters is a must and not a safety hazard in the era of EP sustainability. EHRA Congress; 18.04.2023; Barcelona: University of Antwerp; 2023.

[38] European Commission. National competent authorities. 2023. Available from https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en (accessed: 31.01.2023).

[39] European Commission. Internal Market, Industry, Entrepreneurship and SMEs: Nando (New Approach Notified and Designated Organisations) Information System. 2023. Available from: https://ec.europa.eu/growth/tools-databases/nando/ (accessed 30 January 2023).

[40] Eurostat. Healthcare services. 2023. Available from https://ec.europa.eu/eurostat/web/gisco/geodata/reference-data/healthcare-services (accessed: 15.02.2023).

[41] European Hospital and Healthcare Federation. Members & Representatives. 2023. Available from https://hope.be/membersandrepresentatives/ (accessed: 15.02.2023).

[42] European Union of Private Hospitals. Members. 2023. Available from https://www.uehp.eu/members/ (accessed: 15.02.2023).

Annexes

Annex I: Article 17 MDR

Single-use devices and their reprocessing

1. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.

3. By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;

(b) the reprocessing is performed in accordance with the CS detailing the requirements concerning:

risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,

- the validation of procedures for the entire process, including cleaning steps,
- the product release and performance testing,

- the quality management system,
- the reporting of incidents involving devices that have been reprocessed, and
- the traceability of reprocessed devices.

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

4. Member States may choose to apply the provisions referred to in paragraph 3 also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.

5. The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2020. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with the CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.

6. Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2020 in accordance with Directive 93/42/EEC, may be reprocessed.

7. Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.

8. The name and address of the legal or natural person referred to in paragraph 2 and the other relevant information referred to in Section 23 of Annex I shall be

indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Annex II: Project-related glossary

Glossary of single-use devices and reprocessing terms

Working definitions of terms for the “Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market”

Version: May 2023 (1.0)

In the context of the implementation of Regulation (EU) 2017/745 on medical devices, the European Commission (EC) via the European Health and Digital Executive Agency (HaDEA) commissioned a **study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market** to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (S&P Global) and Civic Consulting.

This glossary provides **working definitions for the study** and includes terms from Regulation (EU) 2017/745 on medical devices, Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices and further sources.

It is important to mention that there is still a lack of understanding among some stakeholders in the EU of what the term “reprocessing” means. “Refurbishing” or “remanufacturing” are often used as synonyms, despite the fact that these terms have a different meaning than reprocessing (EC 2020a). Thus, this glossary aims to clarify the meaning of these terms and to enable a common understanding in the context of this study.

Terms are **listed alphabetically** in the glossary.

Please cite as: Windisch, Friederike; Zimmermann, Nina; Knoll, Verena; Habimana, Katharina; Steigenberger, Caroline; Vogler, Sabine (2023). Glossary of single-use devices and reprocessing terms: Working definitions of terms for the “Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market”. Gesundheit Österreich: Vienna. Available at: https://ppri.goeg.at/Study_Article17MDR

Glossary of terms related to single-use devices and reprocessing

Term	Definition	Source
Actor	Umbrella term for persons and entities which comprises authorities, market players and stakeholders.	WHO CC 2023
AIMDD	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws relating to active implantable medical devices. This EU Directive was valid until 25 May 2021 and was replaced by the MDR.	AIMDD 1990
Authorised representative (AR)	Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation [MDR].	MDR (EU) 2017/745
Authority responsible for notified bodies	Entity or separate constituent entities that, under national law, are responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.	MDR (EU) 2017/745
Authority/ Competent Authority	Government entity responsible for designing the regulatory framework and implementing policies (e.g. ministries, public agencies). In the European context, the term "competent authority" is frequently used.	WHO CC 2023
CE marking of conformity/ CE marking (CE)	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Regulation (EU) 2017/745 and other applicable Union harmonisation legislation providing for its affixing. *Note: The addition of a four-digit number indicates that a notified body was involved in the conformity assessment process.*	MDR (EU) 2017/745 Medical Devices Glossary 2022
Cleaning	Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use.	FDA 2015
Common Specifications (CS)	A set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.	MDR (EU) 2017/745
Conformity assessment	The process demonstrating whether the requirements according to Regulation (EU) 2017/745 relating to a device have been fulfilled.	MDR (EU) 2017/745
Conformity assessment body	A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.	MDR (EU) 2017/745
Cross-infection	Cross infection refers to the transmission of a pathogenic organism from one person to another.	Gale 2020
Declaration of conformity (DoC)	A mandatory document that a manufacturer or an authorised representative need to sign to declare that the products comply with the EU requirements. By signing the DoC, the manufacturer or the authorised representative takes full responsibility for their product's compliance with the applicable EU law.	EC2022a
Decommissioning	Removal of medical devices from their originally intended uses in a health care facility to an alternative use or disposal.	WHO 2019
Decontamination	Removal of soil and pathogenic microorganisms from objects so they are safe to handle, subject to further processing, use or discard.	WHO & PAHO 2016
Device deficiency	Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer.	MDR (EU) 2017/745

Term	Definition	Source
Disinfection	A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilisation processes. The lethality of the disinfection process may vary, depending on the nature of the disinfectant.	FDA 2015
Economic operator (EO)	A manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) MDR.	MDR (EU) 2017/745
End user	End users can be patients, consumers, or professional who directly use the medical device on patients/consumers.	WHO CC 2023
Endotoxin	Endotoxins form part (the lipopolysaccharide complex) of the outer membrane of the cell wall of Gram-negative bacteria. The toxin is released when the cell wall of the bacteria is destroyed.	Pharmaceutical Technology 2023
European Database on Medical Devices (EUDAMED)	EUDAMED is the electronic system established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. With reference to the Articles of Regulation (EU) 2017/745, it includes: a) the electronic system for registration of devices referred to in Article 29(4); b) the UDI database referred to in Article 28; c) the electronic system on registration of economic operators referred to in Article 30; d) the electronic system on notified bodies and on certificates referred to in Article 57; e) the electronic system on clinical investigations referred to in Article 73; f) the electronic system on vigilance and post-market surveillance referred to in Article 92; g) the electronic system on market surveillance referred to in Article 100.	MDR (EU) 2017/745 EC 2021
European Medical Device Nomenclature (EMDN)	The European Medical Device Nomenclature (EMDN) is a nomenclature for medical devices and in vitro diagnostic medical devices.	EC 2023a
External reprocessor	The entity reprocessing single-use devices at the request of a health institution.	EC 2020b
Fully refurbishing	Fully refurbishing, for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device.	MDR (EU) 2017/745
Health care provider	An organisation or person who delivers appropriate health care in a systematic way professionally to any individual in need of health care services.	WHO CC 2023
Health institution	An organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.	MDR (EU) 2017/745
Hospital Acquired Infection	Infections acquired in a hospital by a patient who was admitted for a reason other than that infection. Any infectious agent has the potential to be transmitted nosocomially, whether a bacterium, virus, fungus, parasite, or prion.	WHO 2002

Term	Definition	Source
Implantable device	Any device, including those that are partially or wholly absorbed, which is intended: » to be totally introduced into the human body, or » to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.	MDR (EU) 2017/745
Importer (IM)	Any natural or legal person established within the Union that places a device from a third country on the Union market.	MDR (EU) 2017/745 MDCG 2021-27
Informed consent	A subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation.	MDR (EU) 2017/745
In-house reprocessing	Reprocessing done by the health institution (e.g.: hospital).	EC 2020a
Intended purpose (IP)	The use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.	MDR (EU) 2017/745
Invasive device	Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.	MDR (EU) 2017/745
Label	The written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.	MDR (EU) 2017/745
Legacy device	Devices, which, in accordance with Article 120(3) MDR and Article 110(3) IVDR, are placed on the market after MDR or IVDR dates of application respectively and until 26 May 2024, or until the relevant certificate becomes void, if certain conditions are fulfilled: » devices which are class I devices under Directive 93/42/EEC, for which a declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body; » devices covered by a valid certificate issued in accordance with Directives 90/385/EEC or 93/42/EEC prior to 26 May 2021; » devices covered by a valid certificate issued in accordance with Directive 98/79/EC prior to 26 May 2022.	MDCG 2021-13
Making available on the market	Any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.	MDR (EU) 2017/745
Manufacturer (MF)	A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under his name or trademark.	MDR (EU) 2017/745

Term	Definition	Source
Market surveillance	The activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.	MDR (EU) 2017/745
MDD	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. This EU Directive was valid until 25 May 2021 and was replaced by the MDR.	MDD 1993
Medical device (MD)	Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: » diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, » diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, » investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state, » providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: » devices for the control or support of conception » products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.	MDR (EU) 2017/745
Medical Device Coordination Group (MDCG)	A group of experts, selected based on their expertise and experience in the field of medical devices and in vitro diagnostic medical devices, representing the competent authorities of the Member States and performing the specific tasks set out in Article 105 to Regulation (EU) 2017/745.	MDR (EU) 2017/745
Medical Device Regulation (MDR)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	MDR (EU) 2017/745
New Approach Notified and Designated Organisations (NANDO)	This information system, maintained by the Directorate General Internal Market, Industry, Entrepreneurship and SMEs of the European Commission, provides an overview and information on notified bodies of the European Union.	EC 2023b
Non-EU manufacturer / Foreign manufacturer	A manufacturer of medical devices outside the European Union (EU) or European Economic Area (EEA). For trade in medical devices of the Non-EU manufacturer within the EU/EEA, the manufacturer must have an authorised representative whose place of business must be in one of the EU/EEA Member States.	EC 2020c Medical Devices Glossary 2022
Notified body (NB)	A conformity assessment body designated in accordance with MDR.	MDR (EU) 2017/745
Original device	A new, unused single-use device.	WHO & PAHO 2016

Term	Definition	Source
Outsourcing	The assignment of tasks to an external provider.	ECHAlliance Group 2021
Placing on the market	The first making available of a device, other than an investigational device, on the Union market.	MDR (EU) 2017/745
Prion diseases	A disease due to a prion, a proteinaceous infectious particle that lacks nucleic acids.	MedicineNet
Prions	A disease-causing agent that is neither bacterial nor fungal nor viral and contains no genetic material. Prions are composed largely, if not entirely, of an altered formal (an abnormal isoform) of a normal cellular protein.	MedicineNet
Putting into service	The stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose.	MDR (EU) 2017/745
Refurbishing	Refurbishing is the extensive re-manufacturing of a medical device, which goes beyond reprocessing.	EC 2020a
Remanufacturing	The processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished medical device that significantly changes the finished device's performance or safety specifications, or intended use.	FDA 2022
Reprocessing	The process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation, and related procedures, as well as testing and restoring the technical and functional safety of the used device.	MDR (EU) 2017/745
Reprocessing cycle	A cycle that includes all reprocessing steps applied to a single-use device to ensure that the safety and performance of the reprocessed device is equivalent to that of the original device.	EC 2020b
Reprocessor	The health institution and the external reprocessor reprocessing single-use devices.	EC 2020b
Reusable medical devices	A medical device that is intended for repeated or multiple uses, for which instructions for reprocessing (decontamination, cleaning, disinfection or sterilization) between uses as well as the limits for reprocessing and reuse are provided.	WHO 2019
Reuse	The repeated use or multiple use of any medical device including devices intended for reuse or single use, with reprocessing (cleaning, disinfection, or sterilization) between uses.	FDA 2001
Risk	The combination of the probability of occurrence of harm and the severity of that harm.	MDR (EU) 2017/745
Risk classes for medical devices	The classification of a device according to its intended purpose and the Annex VIII of the MDR. The risk classes, from low to high risk, are: » Class I - Class I medical devices with a measuring function (Im) - Class I sterile medical devices (Is) - Class I reusable surgical instruments (Ir) » Class IIa » Class IIb » Class III	MDR (EU) 2017/745

Term	Definition	Source
Single registration number (SRN)	The registration number that is automatically assigned by EUDAMED to manufacturers, authorised representatives, system and procedure pack producers and importers through the release of an EUDAMED application in the Actor Module by the competent authority in accordance with Articles 31 MDR and 28 IVDR.	MDCG 2021-13
Single-use device	A device that is intended to be used on one individual during a single procedure.	MDR (EU) 2017/745
Small and medium-sized enterprises (SMEs)	Enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. » Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. » Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.	EC2003
Stakeholder	A person or organisation with a legitimate interest in a topic related to health care. Stakeholders may be: » Medical devices or pharmaceutical manufacturers » Equipment suppliers » Patient organisations » Organisations representing health care professionals » Other health care organisations » Civil society organisations	WHO CC 2023
Sterilisation	A validated process used to render the product free from viable microorganisms. *Note: In a sterilisation process, the nature of microbial inactivation is described as exponential and, thus, the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.*	FDA 2015
Sustainability	The capacity to meet the needs of the present without compromising the ability to meet future needs.	WHO CC 2023
System/procedure pack producers (SPPP)	A natural or legal person who manufactures systems or procedure packs according to MDR.	MDR (EU) 2017/745
Traceability	The ability to fully trace a device through its entire lifecycle, from when it is manufactured through to end of life.	HPRA 2010
Unique Device Identification (UDI)	A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.	MDR (EU) 2017/745
Withdrawal	Any measure aimed at preventing a device in the supply chain from being further made available on the market.	MDR (EU) 2017/745

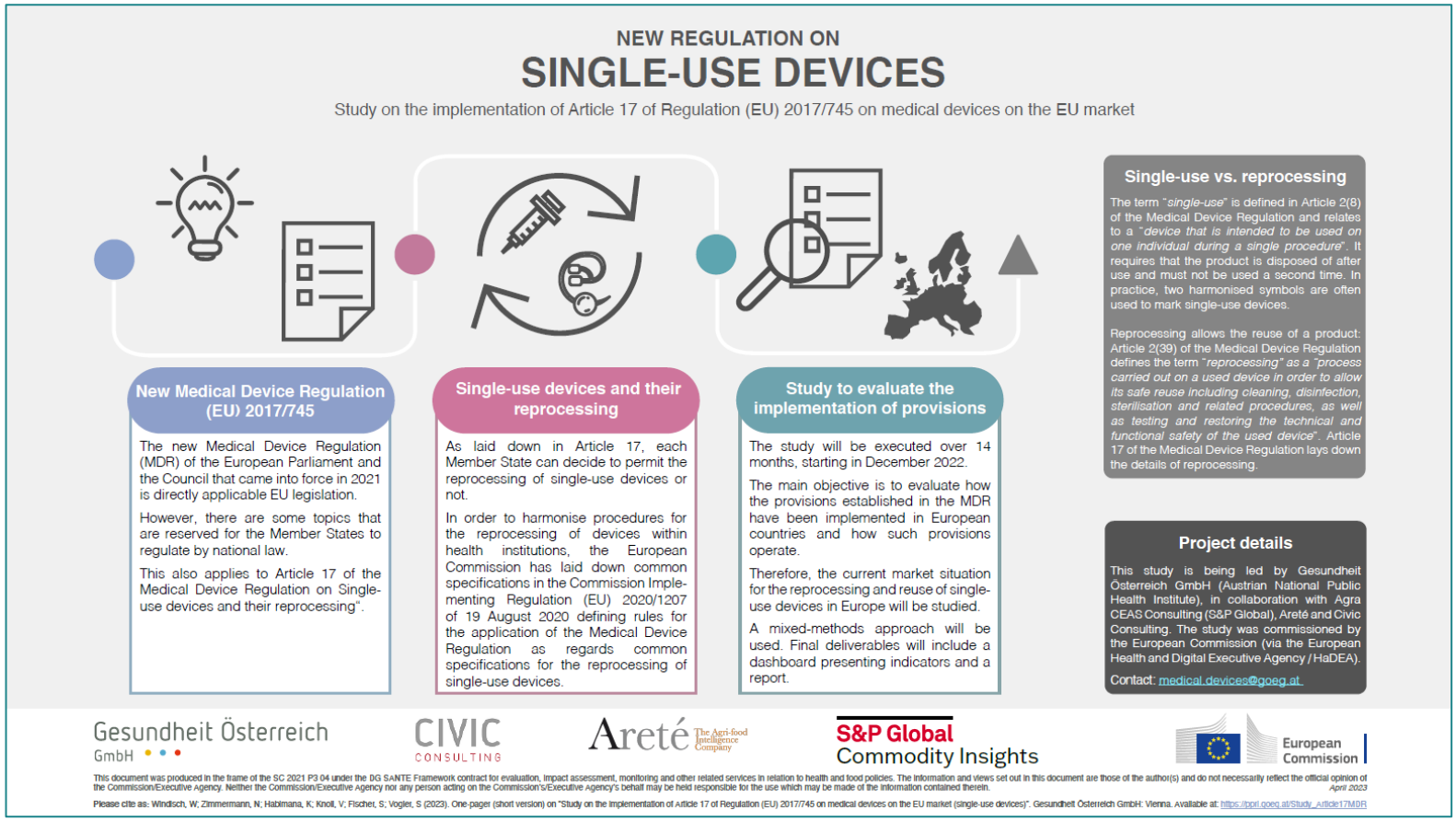
Source: data sources listed in the table

Annex III: One-pager

Figure 5: One-pager long version

Source: the contractor

Figure 6: One-pager short version



Source: the contractor

Annex IV: Literature review

Annex IVa: Literature search strategy

Table 11: Literature search strategy

Type	Search strategy	Activities undertaken
Pragmatic literature search	**Grey literature in English** Search on the websites of the **following institutions**: • European Union (European Commission, particularly of DG SANTE, DG ENTR / DG COMP, DG Research, European Parliament, Council of the EU, project databases, EUROSTAT) • OECD • WHO publications • World Bank publications • PPRI website (and PPRI Intranet, only accessible to PPRI network members) • national and international MD competent authorities • notified bodies • medical devices industry / economic operators and interest associations • governmental homepages (e.g. Ministries of Health) • national statistics institutes (e.g. Statistics Netherlands, Federal Statistical Office Germany) • Google Scholar • several expert networks (e.g. EUPHA, EuroHealthNet, EUnetHTA, INAHTA, PPRI) • health data bases e.g. EUROSTAT, WHO Health for all databases to identify documents which provide information related to the study questions Screening of the websites and use of search terms: medical device(s) AND reprocessing AND/OR single-use/single use. For quality assurance, repetition of the search in Google.	The initial search was conducted on the listed websites and in Google Scholar on **27-31 January 2023**. Reading and inclusion in Endnote® took place up to the end of the study. The search was continued on the listed website continuously throughout the study
Pragmatic literature search	**Grey literature in MSs' national languages (German and English)** Search on the websites of the **following institutions**, with the support of Google Translate or DeepL, where needed: • national MD agencies • notified bodies • medical devices industry and their interest associations to identify documents which provide information related to the study questions. Screening of the websites and use of search terms ("medical device" and "reprocess*" in national languages) Repetition of the search in Google	Search completed and included in Endnote®

Type	Search strategy	Activities undertaken
Targeted literature review	**Peer-reviewed literature** Preliminary search strategy as follows: **Search terms:** ((Medical device*AND (reprocess*)) AND/OR (single-use)) AND/OR (re-use)) OR (barriers)) OR (obstacles)) OR (enablers)) OR (advantages)) OR (disadvantages)) OR (stakeholders)) OR (data)) OR (EU market)) OR (regulation)) OR (medical waste)) References were scanned until saturation was reached (after 100 and 300 references, depending on the search). **Additional criteria**: • only articles published after 2017 were included; • languages were English and German; • the focus was on EU MSs + IC, LI, NO. Snowballing: Scan of the references in the identified literature	Initial literature search conducted in PubMed **on 31 January 2023 and updated on 2 February 2023**, based on a refined, iterative search strategy. Selection of identified literature (scan of titles and, if appropriate, of the abstracts). Continuously monitored throughout the study period and literature included in the analysis. Literature was included in the project's Endnote® folder.

Source: the contractor

Annex IVb: Results of the literature review

Table 12: Results of the literature review

		Description	Reference
National regulations on the reprocessing of SUDs	Ireland	• If a company performs reprocessing, it is the legal manufacturer of the device. • Applicable MDR requirements must be fulfilled when reprocessing, including conformity assessments, traceability, or labelling.	Health Products Regulatory Authority (2017) [20].
	Germany	• Reprocessing may be carried out by an external service provider if it is ensured that the HI will receive its own medical devices back. • Certification of the quality management system by a notified body is a prerequisite for the processing of "Critical C" medical devices. • The German Medical Devices Information and Database System must be contacted before the reprocessing of SUDs.	Kompetenzzentrum Hygiene und Medizinprodukte (2021) [21].
	Sweden	• The reprocessing of SUDs that follows a validated protocol is considered patient safe. • HIs have the possibility to hire an external reprocessor. • There are no restrictions or prohibitions regarding external reprocessing in other EU MSs in Sweden. • There are no restrictions or prohibitions related to the types of products that can be reprocessed in Sweden. • In the literature, the authors of this study did not find any major differences in patient safety between reprocessed and new products.	Socialstyrelsen (2022) [5].
	International	• US: the FDA regulates the reprocessing of SUDs. Solely third-party reprocessors are allowed to reprocess single-use devices. Reprocessing standards are predominantly driven by the determined level of risk for patients.	Johnson+Johnson (2019) [22], Chang et al. (2019) [18].

		Description	Reference
Reasons for reprocessing SUDs	Reasons for allowing reprocessing	• Justification for reprocessing of SUDs on the basis of economic and environmental benefits. • Studies found no increased risk regarding the use of reprocessed SUDs in comparison to the use of new SUDs. • Reprocessing through third-party reprocessors allows for cost reduction for health facilities and may increase innovative technologies and therapies for disease treatment. • Applying circular economy principles to the management of medical devices is often deemed to be the best solution for increasing the environmental efficiency of the products. • Reprocessing as a solution in times of shortages due to the pandemic (COVID-19). • One study compared the reported defect rates of OEM (Original Equipment Manufacturer) and reprocessed single-use bipolar and ultrasound diathermy devices. The findings revealed that OEM bipolar and ultrasound diathermy devices were reported as being defective significantly more frequently than to comparable reprocessed devices.	MHRA (2019) [9], De Sousa Martins et al. (2018) [4], Costa et al. (2019) [3], Benedettini (2022) [11], FAMHP (2021) [23], GAO (2008) [24], Loftus (2015) [25], Crawford & Eagle (2018) [26].
	Reasons for not allowing reprocessing	• Single-use devices have not undergone extensive testing, validation or documentation to ensure that the devices are safe to reuse. • Paucity of data regarding patient safety, effectiveness and clinical impact of certain reprocessed SUDs.	MHRA (2019) [9], Renton et al. (2018) [10], Joint Commission International (2017) [8].
Challenges of reprocessing SUDs	Potential health risks	• Possible cross-infection. • Transmission of abnormal prion proteins during surgical procedures	WHO (2019) [27], MHRA (2019) [9], Renton et al. (2018) [10], PAHO & WHO [28].
	Change to device through reprocessing	• Inadequate cleaning, decontamination and removal of pyrogens and material alteration. • Changes in properties or degradation of the device material. • Absorption of residues of chemical cleaning agents by the material. • Impairment in the quality of devices. • Reactions to endotoxins. • Transmission of abnormal prion proteins during surgical procedures.	WHO (2019) [27], MHRA (2019) [9], Renton et al. (2018) [10], WHO (2022) [29], PAHO & WHO [28], Duncker et al. (2020) [13].
	Issue of liability	• The entity that reprocesses a medical device becomes the new "manufacturer", with the associated responsibilities. • Responsibility of informing patients.	Grantcharov et al. (2019) [30], WHO (2019) [27].
	Ethical considerations	• Reuse of products (e.g. implants). • Patient informed consent. • Equal access to the same level of treatment. • Traceability to patients (in case of adverse events). • Potential asymmetric benefit and risk between patient (e.g. possible health risk) and HI (e.g. cost savings).	European Commission (2020) [31], WHO (2019) [27], Joint Commission International (2017) [8], Chang et al. (2019) [18].

		Description	Reference
	Lack of knowledge and practice	• Limitations to cleaning personnel in their abilities to perform specific cleaning procedures due to lack of equipment, training and time.	Joint Commission International (2017) [8].
	Differences in the suitability of devices	• Critical surfaces of some SUDs are almost impossible to clean and confirm that all possible contaminants have been removed. • Increasing intricacy of reprocessing complex devices.	Joint Commission International (2017) [8], Chang et al. (2019) [18], PAHO & WHO [28].
	Practices of manufacturers	• Manufacturers might upclassify device risk, which results in overstating the difficulty of reprocessing. • US: In order to maximise consumption and profits, companies are incentivised to create SUD that are not reprocessable.	MacNeill et al. (2020) [15], Hennein et al. (2022) [16].
Benefits of reprocessing SUDs[1]	Economic impact	• Cost savings associated with the reprocessing of SUDs might be higher than 90% when the reprocessing is performed in house and 50% when the reprocessing is performed by an external party. • A study in Portugal found differences in acquisition costs of 52% per device. • Potential savings of up to $3,000 per procedure.	De Sousa Martins et al. (2018) [4], Benedettini (2022) [11], Duncker et al. (2020) [13].
	Environmental benefit	• Lower hospital waste production. • A study found waste reduction in hospitals of 40% for a sleeve gastrectomy, 70% for a gastric bypass to 62% for a VATS lobectomy. • In the US, reprocessing saves around 935 tons of medical waste per year. • A study conducting a sensitivity analysis on reprocessed catheters demonstrated a long-term reduction in emissions of approximately 48% per catheter life. • The findings of another study comparing the use of a remanufactured catheter as an alternative to a newly manufactured one revealed a 50.4% reduction in global warming impact and a 28.8% decrease in abiotic resource use.	Costa et al. (2019) [3], Meissner et al. (2021) [32], Kane et al. (2018) [33], Meister et al. (2022) [6], Schulte et al. (2021) [7].
	Solution for shortages	• Techniques for reprocessing single-use personal protective equipment include vaporised hydrogen peroxide (VHP) and UV irradiation technologies, which were likely to be utilised in Ireland during COVID-19 shortages.	Rowan & Laffey (2020) [34].
	Increase in competition	• A study found a significant increase in applications for new devices by original manufacturers after the introduction of reprocessed devices.	Prasad (2020) [35].
	Increasing availability for patients	• 42% of participants in a survey among young EP members declared that making EP procedures available to more patients is a major benefit of reprocessing single-use catheters.	Duncker et al. (2020) [13].

		Description	Reference
Stakeholder perspectives regarding the reprocessing of SUDs	Common perspectives	• Reprocessing may contribute to reducing healthcare spending, combined with a solid regulation to ensure patient safety. • Doubts regarding the prevention of infections, consumer behaviour and regulatory structures. • Lack of trust in reprocessing procedures due to the paucity of data. • Acceptance of reprocessed SUDs among stakeholders if safety and low prices are guaranteed. • Some stakeholders eschew the reprocessing of SUDs over doubts for patient safety and potential delays in the delivery of care.	Bayrak et al. (2021) [12], MacNeill et al. (2020) [15], Kane et al. (2018) [33], Wang et al. (2019) [36], Benedettini (2022) [11].
	Industry, manufacturers	• Manufacturers want to reach a new customer segment by introducing reprocessing. • Large manufacturers consider reprocessing in collaboration as customers aim to decrease their supplier base and establish strategic relationships with only a few suppliers. • Industry prefers reprocessing through external institutions over in-house reprocessing. • Reprocessing of SUDs requires strong regulation. • The industry's progress related to reprocessing SUDs will likely depend on how governments and regulatory stakeholders maintain and update regulations.	Benedettini (2022) [11], Bayrak et al. (2021) [12].
	Health institutions	• Concerns about liability, costs and complexity of reprocessing. • Compatibilities with hospital priorities varies regarding reprocessing (e.g. cost savings vs. decreased functionality of reprocessed devices).	Bayrak et al. (2021) [12], MacNeill et al. (2020) [15], Hennein et al. (2022) [16].
	Healthcare personnel	• The physician's preference for SUDs plays a major role in determining which products are reprocessed. • An online survey among 202 EHRA Young EP members and members of national EP working groups was conducted. The study found that the most frequently reprocessed EP materials include cables (70%), diagnostic EP catheters with deflectable (64%) or fixed curve (63%) catheters among others. The most durable material was diagnostic EP catheters with a fixed curve (61%) while the most sensitive material was ablation catheters with contact force sensors (21%). • An online questionnaire among Croatian surgeons found that more than 90% of participants (n=53) reused single-use surgical equipment. More than 50% reused many single-use devices such as harmonic scalpels, bipolar dissectors, staplers, single-use trocars, graspers, and scissors. Only 5.6% knew about the current legal regulations and future changes in the law.	Hennein et al. (2022) [16], Mihanovic et al. (2021) [14], Duncker et al. (2020) [13].
	Policy-makers	• Due to their beliefs about the increased safety of disposable devices, regulatory bodies tend to prefer single-use disposables over reprocessed ones.	Bayrak et al. (2021) [12], MacNeill et al. (2022) [15].
	Patients	• Patients want to be informed by healthcare personnel about the use of reprocessed SUD.	Grantcharov et al. (2019) [30].

		Description	Reference
Recommendations	Risk Management	• Risks have to be estimated through a risk management plan; a quality management system with recommendations on reprocessing is also needed. • Technical and geometrical characteristics of SUD need to be considered in risk management.	Costa et al. (2019) [3], Bayrak et al. (2021) [12], European Commission (2020) [31].
	Regulatory requirements	• Need for detailed protocols, SOPs and quality management systems for reprocessing. • Identification of suitable products to reprocess • Process to determine if a device is no longer safe to use after reprocessing. • Stakeholders requested a special module on reprocessing on tracking systems such as EUDAMED.	Bayrak et al. (2021) [12], Joint Commission International (2017) [8], Silva et al. (2022) [17], Hennein et al. (2022) [16], PAHO & WHO [28].
	Involvement of stakeholders	• Policies must be determined by all stakeholders in the supply chain. • Extended producer responsibility: MFs are given increased responsibility for the environmental impacts of devices they bring to market. • Providing staff education on reprocessing increases compliance. • Building a business case around reprocessable devices e.g. catheters.	Silva et al. (2022) [17], MacNeill et al. (2022) [15], Hennein et al. (2022) [16], Heidbuchel (2023) [37].
Regulatory aspects	Unclear policies	• Different understanding of the requirements for reprocessing and the delivery of quality patient care that is safe and ethical. • Study findings show that stakeholders in some countries find legislation insufficient. • A lack of clear guidelines created confusion around the standards for reprocessing procedures.	Chang et al. (2019) [18], Benedettini et al. (2022) [11], Silva et al. (2022) [17], MacNeill et al. (2022) [15].

Abbreviations:
FDA: Food and Drug Administration; MDR: medical device regulation; SOP: standard operating procedure; SUDs: single-use device(s)

Source: data sources listed in the table

Annex V: Contact lists for consultation activities

Competent authorities

Table 13: National competent authorities for medical devices in the EU

Country	Competent authority
Austria	Federal Ministry of Social Affairs, Health Care and Consumer Protection Austrian Federal Office for Safety in Health Care (BASG)
Belgium	Federal Agency for Medicines and Health Products (FAMHP)
Bulgaria	Bulgarian Drug Agency
Croatia	Agency for Medicinal Products and Medical Devices
Cyprus	Cyprus Medical Devices Competent Authority
Czech Republic	State Institute for Drug Control, Medical Devices Branch
Denmark	Danish Medicines Agency
Estonia	Health Board, Medical Devices Department
Finland	Finnish Medicines Agency Fimea, Medical Devices Unit
France	Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) Ministry of Health, Direction Générale de la Santé (DGS)
Germany	Federal Ministry of Health (BMG) Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) Federal Institute for Drugs and Medical Devices (BfArM) Paul Ehrlich Institute, Section Pharmacovigilance 2 Robert Koch-Institute (RKI)
Greece	National Organization for Medicines
Hungary	National Institute of Pharmacy and Nutrition
Ireland	Health Products Regulatory Authority
Italy	Ministry of Health, Directorate General of Medical Devices and Pharmaceutical Services
Latvia	Medical Device Evaluation Department, State Agency of Medicines
Lithuania	The State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania
Luxembourg	Ministry of Health
Malta	Malta Medicines Authority – Medical Devices Unit
Netherlands	Notification & Registration: Ministry of Health, Welfare and Sports CIBG Farmatec-BMC Market Surveillance & Vigilance: Dutch Health and Youth Care Inspectorate (IGJ) Notification of clinical investigations (MDR) and performance studies (IVDR): Central Committee on Research Involving Human Subjects (CCMO)
Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Portugal	Infarmed – National Authority of Medicines and Health Products
Romania	National Agency for Medicines and Medical Devices of Romania
Slovakia	State Institute for Drug Control, Medical Devices Section
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia JAZMP
Spain	Agencia Española de Medicamentos y Productos Sanitarios

Country	Competent authority
Sweden	Swedish Medical Products Agency´ 'Läkemedelsverket', Department of Medical Devices Inspektionen för vård och omsorg (IVO)
Iceland	Icelandic Medicines Agency
Liechtenstein	Office of Public Health
Norway	Statens legemiddelverk/ Norwegian Medicines Agency

Source: the contractor

Notified bodies

Table 14: Notified bodies according to the MDR

Body type	Name	Country
NB 1639	SGS Belgium NV	Belgium
NB 2696	UDEM Adriatic d.o.o.	Croatia
NB 1023	INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s. (INSTITUTE FOR TESTING AND CERTIFICATION) merged with ex-NB 1390	Czech Republic
NB 0537	Eurofins Expert Services Oy	Finland
NB 0598 (ex-0403)	SGS FIMKO OY	Finland
NB 0459	GMED SAS	France
NB 0044	TÜV NORD CERT GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0482	DNV MEDCERT GmbH	Germany
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0494	SLG PRÜF UND ZERTIFIZIERUNGS GMBH	Germany
NB 0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Germany
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Italy
NB 0425	ICIM S.P.A.	Italy
NB 0426	ITALCERT SRL	Italy
NB 0476	KIWA CERMET ITALIA S.P.A.	Italy
NB 0477	Eurofins Product Testing Italy S.r.l.	Italy
NB 0546	CERTIQUALITY S.r.l.	Italy
NB 1282	ENTE CERTIFICAZIONE MACCHINE SRL	Italy
NB 1370	BUREAU VERITAS ITALIA S.P.A.	Italy
NB 1936	TUV Rheinland Italia SRL	Italy
NB 0344	DEKRA Certification B.V.	Netherlands

Body type	Name	Country
NB 1912	Kiwa Dare B.V.	Netherlands
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2460	DNV Product Assurance AS	Norway
NB 1434	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.	Poland
NB 2274	TUV NORD Polska Sp. z o.o	Poland
NB 2265	3EC International a.s.	Slovakia
NB 1304	SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ	Slovenia
NB 0318	CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS	Spain
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 2975	SZUTEST Konformitätsbewertungsstelle GmbH	Germany
NB 2764*	Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi	Turkey
NB 2292*	UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.	Turkey
NB 2803*	HTCert (Health Technology Certification Ltd)	Cyprus
NB 3022*	Scarlet NB B.V.	Netherlands
Total: 42 Notified bodies according to the MDR		

* NBs were designated under the MDR after the initial survey and therefore surveyed in the second round (as part of the survey update)

Source: the contractor

Manufacturers

Table 15 lists national associations of MFs in countries where reprocessing is allowed. These associations were also contacted to specifically reach SMEs working on reprocessing.

Table 15: National manufacturers' associations and trade associations

Country/Region	Association
Belgium	BeMedTech
Croatia	CroMed
Germany	BVMed
Ireland	IBEC – Irish MedTech Association
Netherlands	NefeMed
Sweden	Swedish MedTech
EU	MedTech Europe
US	AMDR

Source: data sources listed in the table

Health institutions

Table 16: Members of the European Hospital and Healthcare Federation (HOPE) for countries where reprocessing SUDs is allowed

Country	Institutions
Belgium	Association Belge des Hôpitaux asbl/ Belgische Vereniging der Ziekenhuizen vzw
Croatia	Ministry of Health of the Republic of Croatia
Germany	Deutsche Krankenhausgesellschaft (DKG) / The German Hospital Federation
Germany	Bundesverband Deutscher Privatkliniken e.V.
Ireland	Irish Department of Health
Netherlands	Nederlandse Vereniging van Ziekenhuizen / Dutch Association of Hospitals
Sweden	SVERIGES KOMMUNER OCH REGIONER / Swedish Association of Local Authorities and Regions

Source: European Hospital and Healthcare Federation (HOPE) 2023

Table 17: Members of the World Federation for Hospital Sterilisation Sciences for countries where reprocessing SUDs is allowed

Country	Institutions
Belgium	vzw Vereniging Sterilisatie in het Ziekenhuis
Belgium	Isabelle
Croatia	Hrvatska Udruga Medicinske Sterilizacije
Germany	Deutsche Gesellschaft für Sterilgutversorgung
Ireland	Irish Decontamination Institute
Netherlands	Vereniging van Deskundigen Steriele Medische Hulpmiddelen
Netherlands	Sterilisatie Vereniging Nederland
Sweden	Swedish Sterile Technical Association

Source: World Federation for Hospital Sterilisation Sciences, WFHS (2023)

Annex VI: Interview guides (both for exploratory and follow-up interviews)

Annex IVa: Interview guides for exploratory interviews

Competent authorities that allow the reprocessing of SUDs

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Exploratory interview guide for competent authorities experienced in reprocessing questions

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (single-use devices and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (now part of S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of single-use MD in Europe will be surveyed.

The study requires at its very early stage the performance of **exploratory interviews with competent authorities experienced in reprocessing single-use devices to better understand the situation and to shape further consultation activities**. You have been **selected as an interview partner** given your expertise and experience in the field.

We kindly ask you to participate in this interview. Should you have any questions, please do not hesitate to contact the study team lead Ms Friederike Windisch (medical.devices@goeg.at) or feel free to ask during the interview.

Procedure

The exploratory interviews are based on a **semi-structured interview guide** (see below); we will again introduce the study at the beginning of the interview. Any questions can be answered during the interview. The semi-

structured format will also allow us to discuss any information that you find important in addition to the questions prepared. Interviews are scheduled for max. **60 minutes**.

Two persons from our side will conduct the exploratory interview together via **online tools or telephone**. If performed via an online tool, we will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. Notes will not be published and are only used project internally to inform the next steps. Aggregated data from the exploratory interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: *"I was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this exploratory interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

1. About the interviewee

1.1. Name and position in the institution.
1.2. What is the role of your institution in the reprocessing of single-use devices?
1.3. How many people work in your institution dealing with the reprocessing of single-use devices?

2. Reprocessing of single-use medical devices in your country

2.1. How are the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) implemented by your country?
2.2. Why is the re-processing of single-use devices allowed in your country?
2.3. Can you provide a current link to national legislation on the reprocessing of single-use devices (law or ordinance)? What is the content of the specific legislation?
2.4. What kind of single-use devices are reprocessed? Do you know why this is the case?
2.5. Do you know how many single-use devices are reprocessed in your country (quantities)?
2.6. How many reprocessors (manufacturers, health care institutions) are operating in your country? Are registries in place to identify reprocessors of single-use devices? If yes – link to the registry? Content of the registry?
2.7. Can manufacturers from other (EU)countries also provide reprocessed single-use devices to your country?
2.8. Do you monitor the activities of reprocessing entities (surveillance)?

2.9. Have there been safety concerns in the past regarding the reprocessed single-use devices?

2.10. How do you assess that the current situation regarding reprocessing of single-use devices differs from the past (before the new regulations)?

3. Challenges related to the reprocessing of single-use devices

3.1. Are there, in your opinion, general obstacles in the policy and/or regulatory environment for the reprocessing of single-use devices in Europe? If so, which?

3.2. What are, in your opinion, general barriers to the reprocessing of single-use devices?

4. Opportunities related to the reprocessing of single-use devices

4.1. What are, in your opinion, general enablers or opportunities to the reprocessing of single-use devices?

5. Solutions/Recommendations

5.1. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers mentioned before?

5.2. What would, in your opinion, be solutions or recommendations to deal with the other barriers mentioned earlier?

5.3. How is the cooperation with other stakeholders in the field (reprocessors: external companies or health care institutions, NBs, other competent authorities, other stakeholders)?

6. Further contributions/information

6.1. Asking for further (national) contacts of relevance to be consulted with / involved in this study.

6.2. Asking for further literature, including relevant data bases and methodological documents.

6.3. Asking for the interest and availability of the experts to be further available in this project (participation in the survey).

6.4. Closing and explanation of further steps (minutes, use of information in study).

Thank you very much for your participation in this interview!

Competent authorities that do not allow reprocessing of SUDs

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Exploratory interview guide for competent authorities of countries where the reprocessing of single-use devices is not allowed

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (single-use devices and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (now part of S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for the reprocessing and reuse of single-use MD in Europe will be surveyed.

The study requires at its very early stage the performance of **exploratory interviews with competent authorities in countries where the reprocessing of single-use devices is not allowed to better understand the situation and to shape further consultation activities**. You have been **selected as an interview partner** given your expertise and experience in the field.

We kindly ask you to participate in this interview. Should you have any questions, please do not hesitate to contact the study team lead Ms Friederike Windisch (medical.devices@goeg.at) or feel free to ask during the interview.

Procedure

The exploratory interviews are based on a **semi-structured interview guide** (see below), we will again introduce the study at the beginning of the interview. Any questions can be answered during the interview. The semi-structured format will also allow us to discuss any information that you find important in addition to the questions prepared. Interviews are scheduled for max. **60 minutes**.

Two persons from our side will conduct the exploratory interview together via **online tools or telephone**. If performed via an online tool, we will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. Notes will not be published and are only used project

internally to inform the next steps. Aggregated data of the exploratory interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: *"I was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this exploratory interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

1. About the interviewee

1.1. Name and position in the institution.
1.2. What is the role of your institution in the reprocessing of single-use devices?
1.3. How many people work in your institution dealing with the reprocessing of single-use devices?

2. Reprocessing of single-use devices in your country

2.1. How are the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) implemented by your country?
2.2. Why is the re-processing of single-use devices not allowed in your country?
2.3. Are there ideas/plans to change it in the near future?
2.4. Can manufacturers from other (EU)countries provide reprocessed single-use devices to your country?
2.5. Can manufacturers from non-EU countries provide reprocessed single-use devices to your country?
2.6. Do you know if reprocessors (manufacturers, health care institutions) are operating in your country?
2.7. Have there been safety concerns in the past regarding reprocessed single-use devices?
2.8. How do you assess that the current situation regarding the reprocessing of single-use devices differs from the past (before the new regulations)?

3. Challenges related to the reprocessing of single-use devices

3.1. Are there, in your opinion, general obstacles in the policy and/or regulatory environment for the reprocessing of single-use devices in Europe / in your country? If so, which?
3.2. What are, in your opinion, general barriers to the reprocessing of single-use devices?

4. Opportunities related to the reprocessing of single-use medical devices

4.1. What are, in your opinion, general enablers or opportunities to the reprocessing of single-use devices?

5. Solutions/Recommendations

5.1. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers mentioned before?

5.2. What would, in your opinion, be solutions or recommendations to deal with the other barriers mentioned earlier?

5.3. How is the cooperation with other stakeholders in the field (reprocessors: external companies or health care institutions, NBs, other competent authorities, other stakeholders)?

6. Further contributions/information

6.1. Asking for further (national) contacts of relevance to be consulted with / involved in this study.

6.2. Asking for further literature, including relevant data bases and methodological documents.

6.3. Asking for the interest and availability of the experts to be further available in this project (participation in the survey).

6.4. Closing and explanation of further steps (minutes, use of information in study).

Thank you very much for your participation in this interview!

Link to the EC website describing the situation in EU countries: https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices/national-rules-reprocessing-single-use-devices_en

Notified bodies

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Exploratory interview guide for notified bodies

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (single-use devices and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (now part of S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for the reprocessing and reuse of single-use devices in Europe will be surveyed.

The study requires at its very early stage the performance of **exploratory interviews with notified bodies to better understand the situation and to shape further consultation activities**. You have been **selected as an interview partner** given your expertise and experience in the field.

We kindly ask you to participate in this interview. Should you have any questions, please do not hesitate to contact the study team lead Ms Friederike Windisch (medical.devices@goeg.at) or feel free to ask during the interview.

Procedure

The exploratory interviews are based on a **semi-structured interview guide** (see below), we will again introduce the study at the beginning of the interview. Any questions can be answered during the interview. The semi-structured format will also allow us to discuss any information that you find important in addition to the questions prepared. Interviews are scheduled for max. **60 minutes**.

Two persons from our side will conduct the exploratory interview together via **online tools or telephone**. If performed via an online tool, we will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. Notes will not be published and are only used project internally to inform the next steps. Aggregated data of the exploratory interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: "I *was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this exploratory interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

1. About the interviewee

1.1. Name and position in the institution
1.2. Is your institution a designated notified body according to the MDR/IVDR and/or AIMDD/MDD/IVDM?
1.3. How many people in your institution work in the field of medical devices and in vitro diagnostic medical devices (counted in FTE) and how many people deal with certification processes for the reprocessing of single-use devices?
1.4. How many certificates did you issue in 2022 in relation to reprocessing of single-use devices? (also in comparison with the total no. of certificates issued)
1.5. How many clients do you have in relation to the reprocessing of single-use devices and where are they located (EU/non-EU) (also in comparison with the total number of clients)?

2. Reprocessing of single-use devices in your country / Certificates

2.1. How are the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) implemented by your country? Do you know how the situation is in other EU countries?
2.2. Can you provide a current link to national legislation on the reprocessing of single-use devices (law or ordinance)? What is the content of the specific legislation?
2.3. Why is the re-processing of single-use devices (not) allowed in your country?
2.4. What kind of single-use devices are reprocessed? Do you know why this is the case?
2.5. What does the certification process for reprocessing look like – for companies and for health care institutions?
2.6. How long does the certification process take on average (from receiving the application to accepting the application to certificate issuance) for the reprocessing of single-use devices (also in comparison with the average time for certification for other MD)?
2.7. How do you deal with the increased workload (e.g. hire more staff, prioritise)?
2.8. Do you also have to deny applications from reprocessing companies?
2.9. How many reprocessors (manufacturers, health care institutions) are operating in your country?

2.10. Can manufacturers from other (EU)countries also provide reprocessed single-use devices to your country?

2.11. How do you assess that the current situation regarding reprocessing of single-use devices differs from the past (before the new regulations)?

3. Challenges related to the reprocessing of single-use devices

3.1. Are there, in your opinion, general obstacles in the policy and/or regulatory environment for the reprocessing of single-use devices in your country / in Europe? If so, which?

4. Opportunities related to the reprocessing of single-use devices

4.1. What are, in your opinion, general enablers or opportunities to the reprocessing of single-use devices?

5. Solutions/Recommendations

5.1. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers mentioned before?

5.2. What would, in your opinion, be solutions or recommendations to deal with the other barriers mentioned earlier?

5.3. How is the cooperation with other stakeholders in the field (reprocessors: companies or health care institutions, competent authorities, other stakeholders)?

6. Further contributions/information

6.1. Asking for further (national) contacts of relevance to be consulted with / involved in this study;

6.2. Asking for further literature, including relevant data bases and methodological documents;

6.3. Asking for the interest and availability of the experts to be further available in this project (participation in the survey).

6.4. Closing and explanation of further steps (minutes, use of information in study)

Thank you very much for your participation in this interview!

Manufacturers

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Exploratory interview guide for reprocessing companies

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (single-use devices and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (now part of S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for the reprocessing and reuse of single-use MD in Europe will be surveyed.

The study requires at its very early stage the performance of **exploratory interviews with economic operators reprocessing single-use medical devices to better understand the situation and to shape further consultation activities**. You have been **selected as an interview partner** given your expertise and experience in the field.

We kindly ask you to participate in this interview. Should you have any questions, please do not hesitate to contact the study team lead Ms Friederike Windisch (medical.devices@goeg.at) or feel free to ask during the interview.

Procedure

The exploratory interviews are based on a **semi-structured interview guide** (see below), we will again introduce the study at the beginning of the interview. Any questions can be answered during the interview. The semi-structured format will also allow us to discuss any information that you find important in addition to the questions prepared. Interviews are scheduled for max. **60 minutes**.

Two persons from our side will conduct the exploratory interview together via **online tools or telephone**. If performed via an online tool, we will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. Notes will not be published and are only used project internally to inform the next steps. Aggregated data of the exploratory interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: *"I was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this exploratory interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

1. About you and your company

1.1. Name and position in the company.
1.2. Is it a European company? Where are the headquarters located? Do you have manufacturing sites / subsidiaries in Europe – if yes, where?
1.3. Is your company a small and medium-sized enterprise[11] (SME)?
1.4. How many people in your company are employed in the field of medical devices (incl. in vitro diagnostics)? And how many deal with the reprocessing of single-use devices?
1.5. In which roles does your company operate (e.g. manufacturer, authorised representative, system & procedure pack producer, importer)? What is your core role?
1.6. Reprocessing of single-use devices:
- Which kinds of and how many different devices do you reprocess and provide to the European market (different product codes)?
- Which risk classes are included in your portfolio and to what extent?
- Is there a difference between reprocessing devices and "single-use" devices?
- How many reprocessed single-use devices do you provide to the different countries (quantities)?

1.7. In which countries in the European market are your reprocessed single-use devices mainly available? How many of all EU Member States do you cover with the provision of reprocessed single-use devices?
1.8. Are you also present on markets outside Europe? If yes, where?
1.9. Who are your clients for reprocessed single-use devices (i.e. health care institutions)?

[11] **Definition SME:** The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ **fewer than 250 persons** and which have an **annual turnover not exceeding EUR 50 million**, and/or an **annual balance sheet total not exceeding EUR 43 million**.' (Source: extract of Article 2 of the annex to Recommendation 2003/361/EC.)

2. Reprocessing of single-use devices in your country

2.1. How are the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) implemented by your country?

2.2. Why is the reprocessing of single-use devices allowed in your country (and not in others)?

2.3. What kind of single-use devices are reprocessed?

2.4. What does the reprocessing process look like in practice, could you briefly describe the process?

2.5. Besides you, how many reprocessors (manufactures, health care institutions) are operating in your country? Are registries in place to identify reprocessors of single-use devices? If yes – link to the registry? Content of the registry?

2.6. Can reprocessing companies from outside the EU also provide reprocessed single-use devices to your country or other EU countries?

2.7. How does the certification process involving notified bodies work for reprocessed single-use devices?

2.8. Have there been safety concerns in the past regarding reprocessed single-use devices?

2.9. How do you assess that the current situation regarding the reprocessing of single-use devices differs from the past (before the new regulations)?

3. Challenges related to the reprocessing of single-use devices

3.1. Are there, in your opinion, general obstacles in the policy and/or regulatory environment for the reprocessing of single-use devices in Europe? If so, which?

3.2. What are, in your opinion, general barriers to the reprocessing of single-use devices?

4. Opportunities related to the reprocessing of single-use devices

4.1. What are, in your opinion, general enablers or opportunities to the reprocessing of single-use devices?

5. Solutions / Recommendations

5.1. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers mentioned before?

5.2. What would, in your opinion, be solutions or recommendations to deal with the other barriers mentioned earlier?

5.3. How is the cooperation with other stakeholders in the field (reprocessors: external companies or health care institutions, NBs, other competent authorities, other stakeholders)?

6. Further contributions/information

6.1. Asking for further (national) contacts of relevance to be consulted with / involved in this study.

6.2. Asking for further literature, including relevant data bases and methodological documents.

6.3. Asking for the interest and availability of the experts to be further available in this project (participation in the survey).

6.4. Closing and explanation of further steps (minutes, use of information in study).

Thank you very much for your participation in this interview!

Annex IVb: Interview guides for follow-up interviews

Competent authorities

Note: For every interview, a custom-made guide was used, depending on the answers that the interviewed organisation provided to the survey.

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Interview guide for national competent authorities

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (SUDs and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of SUDs in Europe will be surveyed.

You have been **selected as an interview partner** given your expertise and experience in the field. Interviews are being conducted by Agra CEAS Consulting (S&P Global). Should you have any questions on the study, please feel free to ask during the interview. You may also contact the study team lead Ms Friederike Windisch (medical.devices@goeg.at).

Procedure

The interviews are based on the following **semi-structured interview guide**. Any questions can be answered during the interview. Please note that **previous information you may have provided to this study in exploratory interviews and/or the survey will be taken into consideration**. The interview guide aims to allow you to provide any **additional information** that you find important, in addition to the questions prepared and information previously provided. Interviews are scheduled for max. **60 minutes**.

Interviews are carried out on MS Teams. We will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. **Notes will not be published and are only used internally for the project purposes.** Anonymised, aggregated information from the interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: *"I was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

Note: Please focus on the questions in black font, unless you have any additional information for any of the questions in grey font. Questions in grey font: information previously provided (exploratory interview and/or survey)

1. About the interviewee

1.1. Name and position in the institution.
1.2. What is the role of your institution in the reprocessing of SUDs?
1.3. How many people work in your institution dealing with the reprocessing of SUDs?
1.4. How is the cooperation with other stakeholders in the field *(reprocessors: external companies or health care institutions, NBs, other competent authorities)*?

2. Reprocessing of single-use devices in your country

2.1. Why did your country decide to grant permission to reprocess (e.g. result of a preliminary study, national debate)?
2.2. What kind of SUDs are reprocessed/reused and why?
2.3. How are the provisions established in Article 17 of the MDR implemented in your country?
2.4. Have restrictions and prohibitions been imposed by your country in accordance with Article 17 (9) MDR?
2.5. How many reprocessors (manufactures, health care institutions) are operating in your country? Are registries in place to identify reprocessors of SUDs? If yes – link to the registry? Content of the registry?
2.6. Can manufacturers from other (EU) countries also provide reprocessed SUDs to your country?
2.7. Regarding reprocessing and/or reuse of SUDs, how would you interpret the current situation in Europe / your country / your institution?
2.8. Does the current situation regarding reprocessing of SUDs differ from the past (before the new regulations) and how?
2.9. Do you monitor the activities of reprocessing entities (surveillance)?
2.10. Have there been safety concerns in the past/currently regarding reprocessed SUDs?

3. Challenges related to the reprocessing of single-use devices

3.1. Do you face any **challenges or issues** with regard to the implementation of the Common Specifications (Regulation (EU) 2020/1207) or more generally with regard to the implementation of Article 17 of the MRD?

3.2. What are, in your opinion, general **obstacles** for the reprocessing of SUDs in Europe?

4. Opportunities related to the reprocessing of single-use devices

4.1. What are, in your opinion, general **opportunities** regarding the reprocessing of SUDs?

5. Actions/Recommendations

5.1. What would, in your opinion, be **actions or recommendations** to deal with the challenges indicated above?

5.2. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers indicated above?

6. Further contributions/information

6.1. Please provide any further (national) contacts of relevance to be consulted with during this study.

6.2. Please provide any further literature, including relevant databases and methodological documents.

Country	National legislation on the reprocessing of single-use devices
Belgium	• 22 December 2020 – Law on medical devices (FR) or Law on medical devices (NL) • 12 May 2021 – Royal decree implementing the law of 22 December 2020 on medical devices (FR)
Croatia	• 5 November 2018 – Law on the Implementation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices (HR)
Germany	• 21 April 2021 – Ordinance on the creation, operation and use of medical devices (Medical Device Operators Regulation - MPBeBetriebV) (DE)
Ireland	• 25 May 2021 – Medical Devices Regulations 2021, S.I. No. 261 of 2021 (EN)
Netherlands	• 24 October 2019 – Act containing rules on the safety and quality of medical devices (Medical devices act), Staatsblad 2019 400 (NL) • 24 April 2020 – Decision containing rules on the reprocessing and further use of single-use devices within Article 17 of Regulation (EU) 2017/745 and further rules on the use of medical devices (Medical devices decision), Staatsblad 2020 130 (NL)
Sweden	• 17 June 2021 – https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2021631-med-kompletterande_sfs-2021-631 (SE)

Thank you very much for your participation in this interview!

Notified bodies

Note: For every interview, a custom-made guide was used, depending on the answers that the interviewed organisation provided in the survey.

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Interview guide for manufacturers

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (single-use devices and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of SUDsin Europe will be surveyed.

You have been **selected as an interview partner** given your expertise and experience in the field. Interviews are being conducted by Agra CEAS Consulting (S&P Global). Should you have any questions on the study, please feel free to ask during the interview. You may also contact the study team lead Ms Friederike Windisch (medical.devices@goeg.at).

Procedure

The interviews are based on the following **semi-structured interview guide**. Any questions can be answered during the interview. Please note that **previous information you may have provided to this study in exploratory interviews will be taken into consideration**. The interview guide aims to allow you to provide any **additional information** that you find important, in addition to the questions prepared and information previously provided. Interviews are scheduled for max. **60 minutes**.

Interviews are carried out on MS Teams. We will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. **Notes will not be published and are only used internally for the project purposes.** Anonymised, aggregated information from the interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: *"I was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

Note: Please focus on the questions in black font, unless you have any additional information for any of the questions in grey font. ***SQ: survey question***

1. About the interviewee

1.1. Name and position in the organisation.
1.2. What is the role of your organisation in reprocessing of SUDs?
1.3. How many people work in your institution dealing with reprocessing of SUDs?
1.4. How is the cooperation with other stakeholders in the field *(health care institutions, NBs, other competent authorities)*?

2. Reprocessing of single-use devices on the EU market

2.1. How are the provisions established in Article 17 of the MDR implemented across the EU?
2.2. Have restrictions and prohibitions been imposed in accordance with Article 17 (9) MDR?
- ***SQ4/5****: Please provide more information on the national provisions in EU Member States where your reprocessed SUDs are made available, drawing on differences or specificities in implementation.*
- *Please explain the reasons why your products are only made available in those MSs and regulatory constraints for making them available in other MSs.*

2.3. How many reprocessors (manufacturers, health care institutions) are operating across the EU? Are registries in place to identify reprocessors of SUDs? If yes – link to the registry? Content of the registry?
2.4. Can manufacturers from other (EU) countries also provide reprocessed SUDs to another country?
2.5. Are the activities of reprocessing entities being monitored and how (surveillance)?
2.6. Have there been safety concerns in the past / currently regarding reprocessed SUDs?

3. Challenges related to the reprocessing of single-use devices

3.1. What are, in your opinion, **challenges or issues** with regard to the implementation of the Common Specifications (Regulation (EU) 2020/1207) or more generally with regard to the implementation of Article 17 of the MRD?

3.2. What are, in your opinion, general **obstacles** for the reprocessing of SUDs in Europe?

- ***SQ17**: fragmented implementation – see also 2.1/2.2 above*

4. Opportunities related to the reprocessing of single-use devices

4.1. What are, in your opinion, general **opportunities** regarding the reprocessing of SUDs?

5. Actions/Recommendations

5.1. What would, in your opinion, be **actions or recommendations** to deal with the challenges indicated above?

- ***SQ19/20: please expand on the solutions/actions identified.***

5.2. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers indicated above?

6. Further contribution/information

6.1. Please provide any further (national) contacts of relevance to be consulted with during this study.

6.2. Please provide any further literature, including relevant data bases and methodological documents.

Country	National legislation on the reprocessing of single-use devices
Belgium	• 22 December 2020 – Law on medical devices (FR) or Law on medical devices (NL) • 12 May 2021 – Royal decree implementing the law of 22 December 2020 on medical devices (FR)
Croatia	• 5 November 2018 – Law on the Implementation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices (HR)
Germany	• 21 April 2021 – Ordinance on the creation, operation and use of medical devices (Medical Device Operators Regulation - MPBeBetriebV) (DE)
Ireland	• 25 May 2021 – Medical Devices Regulations 2021, S.I. No. 261 of 2021 (EN)
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Sweden	• 17 June 2021 – https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2021631-med-kompletterande_sfs-2021-631 (SE)

Thank you very much for your participation in this interview!

Manufacturers

Note: For every interview, a custom-made guide was used, depending on the answers that the interviewed organisation provided to the survey.

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Interview guide for manufacturers

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (single-use devices and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of SUDsin Europe will be surveyed.

You have been **selected as an interview partner** given your expertise and experience in the field. Interviews are being conducted by Agra CEAS Consulting (S&P Global). Should you have any questions on the study, please feel free to ask during the interview. You may also contact the study team lead Ms Friederike Windisch (medical.devices@goeg.at).

Procedure

The interviews are based on the following **semi-structured interview guide**. Any questions can be answered during the interview. Please note that **previous information you may have provided to this study in exploratory interviews will be taken into consideration**. The interview guide aims to allow you to provide any **additional information** that you find important, in addition to the questions prepared and information previously provided. Interviews are scheduled for max. **60 minutes**.

Interviews are carried out on MS Teams. We will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. **Notes will not be published and are only used internally for the project purposes.** Anonymised, aggregated information from the interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: *"I was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

Note: Please focus on the questions in black font, unless you have any additional information for any of the questions in grey font. ***SQ: survey question***

1. About the interviewee

1.1. Name and position in the organisation.
1.2. What is the role of your organisation in the reprocessing of SUDs?
1.3. How many people work in your institution dealing with the reprocessing of SUDs?
1.4. How is the cooperation with other stakeholders in the field *(health care institutions, NBs, other competent authorities)*?

2. Reprocessing of single-use devices on the EU market

2.1. How are the provisions established in Article 17 of the MDR implemented across the EU?
2.2. Have restrictions and prohibitions been imposed in accordance with Article 17 (9) MDR?
- ***SQ4/5****: Please provide more information on the national provisions in EU Member States where your reprocessed SUDs are made available, drawing on differences or specificities in implementation.*
- *Please explain the reasons why your products are only made available in those MSs and regulatory constraints for making them available in other MSs.*

2.3. How many reprocessors (manufacturers, health care institutions) are operating across the EU? Are registries in place to identify reprocessors of SUDs? If yes – link to the registry? Content of the registry?
2.4. Can manufacturers from other (EU) countries also provide reprocessed SUDs to another country?
2.5. Are the activities of reprocessing entities being monitored and how (surveillance)?
2.6. Have there been safety concerns in the past/currently regarding reprocessed SUDs?

3. Challenges related to the reprocessing of single-use devices

3.1. What are, in your opinion, **challenges or issues** with regard to the implementation of the Common Specifications (Regulation (EU) 2020/1207) or more generally with regard to the implementation of Article 17 of the MRD?

3.2. What are, in your opinion, general **obstacles** for the reprocessing of SUDs in Europe?

- ***SQ17**: fragmented implementation – see also 2.1/2.2 above*

4. Opportunities related to reprocessing of single-use devices

4.1. What are, in your opinion, general **opportunities** regarding the reprocessing of SUDs?

5. Actions/Recommendations

5.1. What would, in your opinion, be **actions or recommendations** to deal with the challenges indicated above?

- ***SQ19/20: please expand on the solutions/actions identified.***

5.2. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers indicated above?

6. Further contributions/information

6.1. Please provide any further (national) contacts of relevance to be consulted with during this study.

6.2. Please provide any further literature, including relevant databases and methodological documents.

Country	National legislation on the reprocessing of single-use devices
Belgium	• 22 December 2020 – Law on medical devices (FR) or Law on medical devices (NL) • 12 May 2021 – Royal decree implementing the law of 22 December 2020 on medical devices (FR)
Croatia	• 5 November 2018 - Law on the Implementation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices (HR)
Germany	• 21 April 2021 – Ordinance on the creation, operation and use of medical devices (Medical Device Operators Regulation - MPBeBetriebV) (DE)
Ireland	• 25 May 2021 – Medical Devices Regulations 2021, S.I. No. 261 of 2021 (EN)
Netherlands	• 24 October 2019 – Act containing rules on the safety and quality of medical devices (Medical devices act), Staatsblad 2019 400 (NL) • 24 April 2020 – Decision containing rules on the reprocessing and further use of single-use devices within Article 17 of Regulation (EU) 2017/745 and further rules on the use of medical devices (Medical devices decision), Staatsblad 2020 130 (NL)
Sweden	• 17 June 2021 – https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2021631-med-kompletterande_sfs-2021-631 (SE)

Thank you very much for your participation in this interview!

Health institutions

Note: For every interview, a custom-made guide was used, depending on the answers that the interviewed organisation provided to the survey.

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market (HADEA/2021/P3/04)

Interview guide for health institutions

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market" (single-use devices and their reprocessing). The study started in December 2022 and will be running for 14 months (February 2024). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (S&P Global) and Civic Consulting.

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of SUDs in Europe will be surveyed.

You have been **selected as an interview partner** given your expertise and experience in the field. Interviews are being conducted by Agra CEAS Consulting (S&P Global). Should you have any questions on the study, please feel free to ask during the interview. You may also contact the study team lead Ms Friederike Windisch (Friederike.windisch@goeg.at).

Procedure

The interviews are based on the following **semi-structured interview guide**. Any questions can be answered during the interview. Please note that **previous information you may have provided to this study in exploratory interviews and/or the survey will be taken into consideration**. The guide aims to allow you to provide any **additional information** that you find important, in addition to the questions prepared and information previously provided. Interviews are scheduled for max. **60 minutes**.

Interviews are carried out on MS Teams. We will ask you at the beginning whether the conversation **can or cannot be recorded** to facilitate note taking (for internal purpose only). **Summary notes** will be shared with you in writing for your remarks and validation after the interview. **Notes will not be published and are only used internally for the project purposes.** Anonymised, aggregated information from the interviews may be published at a later stage.

Informed consent and acknowledgement

Informed consent: The **interviewee accepts orally to participate in the study**: *"I was informed about the study, and I understand its aims. I agree on participating, on a voluntary basis, in this interview for this study. I understand that there is no remuneration for my participation in the study".*

☐ Yes, I give my informed consent.
☐ No, I do not give my informed consent.

Acknowledgement: Please let us know whether you/your institution would like to be **named in the acknowledgement sections** of documents to be published (final report in 2024).

☐ Yes, I would like to be named in acknowledgement sections, including my affiliation.
☐ No, I would not like to be named in acknowledgement sections, only my institution.
☐ No, I would not like to be named in acknowledgement sections, neither would my institution.

Interview guide

1. About the interviewee

1.1. Name and position in the institution.
1.2. What is the role of your institution in reprocessing of SUDs?
  1.2.1. Do you reprocess SUDs at your health institution (in-house)?
  1.2.2. Are you reusing SUDs at your health institution?
  1.2.3. Do you also buy SUDs from external reprocessors?
1.3. How many people work in your institution dealing with the reprocessing of SUDs?
1.4. How is the cooperation with other stakeholders in the field *(reprocessors: external companies or health care institutions, NBs, other competent authorities)*?

2. Reprocessing of single-use devices in your country

2.1. How are the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) implemented in your country?
2.2. What kind of SUDs are reprocessed/reused? Do you know why this is the case?
2.3. How many reprocessors (manufacturers, health care institutions) are operating in your country? Are registries in place to identify reprocessors of SUDs? If yes – link to the registry? Content of the registry?
2.4. Can manufacturers from other (EU) countries also provide reprocessed SUDs to your country?
2.5. Regarding reprocessing and/or reuse of SUDs, how would you interpret the current situation in Europe / your country / your institution?
2.6. Does the current situation regarding reprocessing of SUDs differ from the past (before the new Regulations) and how?
2.7. Do you monitor activities of reprocessing entities (surveillance)?
2.8. Have there been safety concerns in the past/currently regarding reprocessed SUDs?

3. Challenges related to reprocessing of single-use devices

3.1. Do you face any challenges with regard to the implementation of the Common Specifications or national provisions *(e.g. in relation to: risk management system; validation of procedures; product release and performance testing; quality management system; reporting of incidents; traceability of reprocessed devices)*?

3.2. Are there, in your opinion, obstacles in the policy and/or regulatory environment for the reprocessing / reuse of SUDs in Europe? If so, which?

3.3. What are in your opinion, as a stakeholder, barriers to the reprocessing /reuse of SUDs?

4. Opportunities related to the reprocessing of single-use devices

4.1. What are in your opinion, as a stakeholder, enablers or opportunities to the reprocessing / reuse of SUDs?

5. Solutions/Recommendations

5.1. Can you provide any examples from your experience with reprocessing (procedures) that helped reduce and/or remove any of the barriers indicated above?

5.2. What would, in your opinion, be solutions or recommendations to deal with the barriers indicated above?

6. Further contributions/information

6.1. Please provide any further (national) contacts of relevance to be consulted with during this study.

6.2. Please provide any further literature, including relevant data bases and methodological documents.

Country	National legislation on the reprocessing of single-use devices
Belgium	• 22 December 2020 – Law on medical devices (FR) or Law on medical devices (NL) • 12 May 2021 – Royal decree implementing the law of 22 December 2020 on medical devices (FR)
Croatia	• 5 November 2018 – Law on the Implementation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices (HR)
Germany	• 21 April 2021 – Ordinance on the creation, operation and use of medical devices (Medical Device Operators Regulation - MPBeBetriebV) (DE)
Ireland	• 25 May 2021 – Medical Devices Regulations 2021, S.I. No. 261 of 2021 (EN)
Netherlands	• 24 October 2019 – Act containing rules on the safety and quality of medical devices (Medical devices act), Staatsblad 2019 400 (NL) • 24 April 2020 – Decision containing rules on the reprocessing and further use of single-use devices within Article 17 of Regulation (EU) 2017/745 and further rules on the use of medical devices (Medical devices decision), Staatsblad 2020 130 (NL)
Sweden	• 17 June 2021 – https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2021631-med-kompletterande_sfs-2021-631 (SE)

Thank you very much for your participation in this interview!

Annex VII: Questionnaire templates for surveys

Overview of targeted questionnaires

Table 18: Targeted questionnaires

Stakeholder group and targeted questionnaires			
Competent authorities	**Notified bodies**	**Manufacturers**	**Health institutions**
Q3-CA1: CAs for medical devices in countries that ALLOW reprocessing **Q4-CA2:** CAs for medical devices in countries that do NOT ALLOW reprocessing **Q5-CA3:** CAs for medical devices in countries who have not yet made a decision regarding reprocessing	**Q1-NB1:** NBs designated under the MDR that certify reprocessed SUDs and/or compliance with Regulation (EU) 2020/1207 (CS) **Q2-NB2:** NBs designated under the MDR that do NOT certify either reprocessed SUDs or compliance with Regulation (EU) 2020/1207 (CS)	**Q6-MF1:** Manufacturers who reprocess SUDs	**Q7-HI1:** Health institutions in countries where reprocessing is allowed, that reprocess and/or reuse SUDs according to the CS

Abbreviations: CA = competent authority/authorities, CS = common specifications, EU = European Union, HI = health institution(s), MF = manufacturer(s), NB = notified body/bodies, Q = questionnaire

Source: the contractor

Competent authorities

Survey part A

Background

According to Article 17 of Regulation (EU) 2017/745 on medical devices, reprocessing of single-use devices is possible only if permitted by national law.

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via the European Health and Digital Executive Agency (HaDEA) – has commissioned a "**Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market**" (single-use devices and their reprocessing).

The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (now part of S&P Global) and Civic Consulting. The study started in December 2022 and will be running for 14 months (February 2024).

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of single-use devices in Europe will be surveyed.

The study requires us to conduct surveys with **different stakeholder groups**:

1) Notified bodies designated under the MDR who certify reprocessed single-use devices and/or compliance with Regulation (EU) 2020/1207 (CS);
2) Notified bodies designated under the MDR who do NOT certify either reprocessed single-use devices or compliance with Regulation (EU) 2020/1207 (CS);
3) Competent authorities on medical devices of Member States that ALLOW reprocessing;
4) Competent authorities on medical devices of Member States that do NOT ALLOW reprocessing;
5) Competent authorities who have not made a decision regarding reprocessing yet;
6) Manufacturers who reprocess single-use devices;
7) Health institutions, in countries where reprocessing is allowed, that reprocess and/or reuse single-use devices.

In particular, the results of the study shall identify possible proposals for amendments to the MDR with regard to the reprocessing of single-use devices.

The survey results will be exported from the EU survey tool, analysed on an aggregated level in the form of reports and might be published in a dashboard

Participation in the survey

We collect data/information from different stakeholder groups and tried to keep the workload for completing the surveys to a minimum. Please note that this is a one-time survey. You can download here the current version of the survey questionnaire.

Instructions on how to answer to the survey:

» Navigate through the questionnaire using the arrow buttons at the end of each page.
» To change replies, it is sufficient to go back to the question and modify it.
» A draft of the survey in progress can be saved via the dedicated button on the right end of each page.
» In some questions, additional instructions can be provided in italics (e.g.: *select one option*, *select all that apply*) – additional instructions will appear in case of errors in the answer (e.g.: "*This is not a valid e-mail address.*")
» Fields marked with (*) are mandatory. In case of missing mandatory replies, an error message ("*This field is required.*") in red is displayed on the relevant section of the question when the respondent moves forward in the questionnaire.
» In multiple choice questions, when the option "none" is selected, all the other selected options (if any) will be ignored.
» To submit your replies please be sure to proceed until the very last page by clicking the "submit" button at the bottom of said page.
» After submitting the questionnaire, this message will be displayed: "We thank you for your time spent taking this survey. Your response has been recorded". A summary of the replies is provided and can be downloaded in PDF or printed.
» You can find a Glossary of the terms used in this survey at the following link: link to glossary

Data protection and consent to participate

Any company specific information (raw data) and personal information of the person responding collected in the survey will be kept confidential. Only aggregated survey outcomes will be published in the data dashboard and analysis reports. We follow the EC privacy statement.

With the submission of your data/information you agree to these terms.

Contact

If you have enquiries, please contact the project coordinator Friederike Windisch (medical.devices@goeg.at).

Please, be aware that only questions applicable to your case will actually be shown to you. The survey self-adapts on the grounds of previous replies. The one included in this file is the full version of the questionnaire: in your case, the survey may be shorter.

About the survey participant

» With the submission of your data/information you agree to publication on an aggregated level. *checkbox "I agree"* *
» Country *drop down – 27 EU-MS; Iceland, Liechtenstein, Norway* *
» Institution *open field*
» Name of the person completing the survey (optional) *open field*
» Role (job title / function) of the person completing the survey (optional) *open field*
» Contact details: phone no (optional) *open field*
» Contact e-mail address *
» Indication of the stakeholder group you belong to: *single-choice (trigger for the right questionnaire)* *

- Competent authorities on medical devices that ALLOW reprocessing (**Q3 – CA1**)
- Competent authorities that do NOT ALLOW reprocessing (**Q4 – CA2**)
- Competent authorities that have not made a decision regarding reprocessing yet (**Q5 – CA3**)

Survey part B:
Q3 (CA1): Questionnaire for competent authorities on medical devices of 27 EU Member States (EU-27), Iceland, Liechtenstein and Norway that ALLOW reprocessing

Implementation of Article 17 MDR in your country

1. Which **national provision(s)** regulate(s) reprocessing and further use of single-use devices in accordance with Article 17(1) MDR in your country? *

a. Name of national provision(s) in **national language** – please state all legal texts: *open field*
b. Name of national provision(s) in **English** (translation): *open field*
c. Which **paragraph or article** in the national provision(s) specifically regulate(s) the reprocessing of single-use devices? *open field*
d. Can you also provide the official **weblink** to the national provision(s)? *open field*
e. When did the national provision(s) **come into force**? *open field*

Article 17(1): *information box*
Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

2. Why did your country decide to grant **permission** (e.g. result of a preliminary study, national debate)? *open field* *

a. If applicable, could you please provide the links to publicly available preliminary studies, national debates, the evidence base for decision making etc.? *open field*

Specific questions on paragraphs of Article 17 MDR since it contains derogation possibilities

Manufacturer obligations

3. **Manufacturer:** Does Article 17(2) MDR **apply** in your country? *
checkbox: "yes", "no"

Article 17(2): *information box*
*Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union **shall be considered to be the manufacturer of the reprocessed device** and **shall assume the obligations incumbent on manufacturers laid down in this Regulation,** which include obligations relating to the **traceability of the reprocessed device** in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.*

Single-use devices that are reprocessed and used within a health institution

4. Did your country decide not to apply all the rules relating to manufacturers' obligations laid down in Article 17(2) **provided that the reprocessing is performed in accordance with Regulation (EU) 2020/1207 (Common Specifications)** – see Article 17(3)? *checkbox: "yes", "no"* *

> ***Article 17(2):*** *information box*
> *Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union* ***shall be considered to be the manufacturer of the reprocessed device*** *and* ***shall assume the obligations incumbent on manufacturers laid down in this Regulation,*** *which include obligations relating to the* ***traceability of the reprocessed device*** *in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.*

> ***Article 17(3) MDR:*** *information box*
> *By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution,* ***Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided*** *that they ensure that:*
>
> *(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;*
> *(b) the reprocessing is performed in accordance with CS detailing the requirements concerning:*
> - *risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,*
> - *the validation of procedures for the entire process, including cleaning steps,*
> - *the product release and performance testing,*
> - *the quality management system,*
> - *the reporting of incidents involving devices that have been reprocessed, and the traceability of reprocessed devices.*
>
> *Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.*
>
> *Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.*

5. **Outsourcing:** Did your country choose to apply the provisions as regards single-use devices that are reprocessed by an **external reprocessor at the request of a health institution according to Article 17(4)** provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in Article 17(3) a and b MDR? *
checkbox: "yes", "no"

> ***Article 17(4) MDR:*** *information box*
> *Member States may choose to apply the provisions referred to in paragraph 3 also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.*

6. Did your country require **health institutions** to **provide information to patients on the use of reprocessed devices within the health institution** and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with? *
checkbox: "yes", "no"

a. If yes, could you please indicate the specific regulation of the requirement to inform patients. *open field*

b. If no, are health institutions encouraged to inform patients and in what form? *open field*

Restrictions and prohibitions of Article 17 in national provisions

7. **Maintain or introduce national provisions that are stricter:** Have restrictions and prohibitions been imposed by your country in accordance with Article 17(9) MDR? *checkbox: "yes", "no"* *

If yes:

a. The reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing. *checkbox: "yes", "no"*

- If yes, which restrictions and prohibitions apply? Please explain in detail. *open field*

b. The making available or further use of reprocessed single-use devices. *checkbox: "yes", "no"*

- If yes, which restrictions and prohibitions apply? Please explain in detail. *open field*

Article 17(9): *information box*
A Member State that permits reprocessing of single-use devices may ***maintain or introduce national provisions that are stricter*** *than those laid down in this Regulation* ***and which restrict or prohibit, within its territory****, the following:*

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

Notification requirements

8. **Notifications according to Article 17(3):** *
Did you already notify
   a. the **European Commission** of the national provisions introduced pursuant to Article 17(3) MDR (manufacturers obligations for health institutions) and the grounds for introducing them? *checkbox: "yes", "no"*

   b. the other **Member States** of the national provisions introduced pursuant to Article 17(3) MDR (manufacturers obligations for health institutions) and the grounds for introducing them? *checkbox: "yes", "no"*

Article 17(3) MDR: *information box*
By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution, ***Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided*** *that they ensure that:*

*(c) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;**
(d) the reprocessing is performed in accordance with the CS detailing the requirements concerning:
- *risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,*
- *the validation of procedures for the entire process, including cleaning steps,*
- *the product release and performance testing,*
- *the quality management system,*
- *the reporting of incidents involving devices that have been reprocessed, and the traceability of reprocessed devices.*

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.
Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

9. **Notifications according to Article 17(9):**
Did you already notify
   a. the **European Commission** about these restrictions and prohibitions pursuant to Article 17(9) MDR? *checkbox: "yes", "no"*

   b. the **Member States** about these restrictions and prohibitions pursuant to Article 17(9) MDR? *checkbox: "yes", "no"*

Article 17(9): *information box*
A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:
(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;
(b) the making available or further use of reprocessed single-use devices.
Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

Other national provisions, guidelines, and specifications

10. Are there any other national provisions, specifications, or further documents (e.g.: guidelines) related to the reprocessing of single-use devices in your country? *checkbox: "yes", "I don't know", "no"* *

    a. If yes, please specify the national provisions, specifications, or further documents and the corresponding paragraph or article and provide a link. *open field*

11. Is there any ongoing discussion on whether to (further) restrict or prohibit the reprocessing of single-use devices? *checkbox: "yes", "I don't know", "no"* *

    a. If yes, please specify the possible restrictions. *open field*

Reprocessing of single-use devices

12. What kind of single-use devices are in your experience reprocessed in your country?

    checkbox "Cardiovascular"; "Arthroscopic/Orthopedic"; "General Surgery"; "Laparoscopic"; "Non-invasive"; "Others"; "I don't know".

    a. Cardiovascular

    - Diagnostic electrophysiology (EP) catheters
    - Ultrasound catheters
    - Intra-cardiac echocardiography catheters
    - Intravascular catheters
    - Mapping catheters
    - Coronary sinus catheters
    - EP cables
    - Introducer sheaths
    - Ablation catheter
    - Transseptal needles
    - Radiofrequency catheter

    b. Arthroscopic/Orthopedic

    - Arthroscopic shavers
    - Arthroscopic wands
    - Bits, burs and blades
    - Shavers
    - External fixation devices and components

    c. General surgery

    - Clamps and dissectors
    - Infusion pressure bags
    - Reamers
    - Suture passers
    - Soft tissue ablators
    - Scissor tips
    - Balloon inflation devices
    - Endoscopic accessories

    d. Laparoscopic

    - Sealers and dividers
    - Ultrasonic scalpels
    - Trocars
    - Laparoscopic instruments including babcocks, dissectors, graspers and scissors

    e. Non-invasive

    - Blood pressure cuffs and tourniquet cuffs
    - Patient fall alarms
    - Air transfer mattresses / HoverMatts
    - Pneumatic tourniquet cuffs
    - Infusor bags
    - Tourniquets
    - EKG and ECG leads and cables
    - Femoral compression devices

- Pulse oximeter sensors
- Sequential compression devices / DVT sleeves

f. Other, please specify *open field*

13. Do you know if reprocessors of SUDs according to MDR Article 17(2) (manufacturers) transfer reprocessed single-use devices from your country to other Member States or non-EU countries?
checkbox: "yes", "I don't know", "no" *

a. If yes, to which Member States and/or non-EU countries are reprocessed single-use devices transferred? *Open field*

14. Can manufacturers from other (EU) countries make available reprocessed single-use devices in your country?
checkbox: "yes", "I don't know", "no" *

Vigilance and market surveillance

15. Who is the competent authority for **market surveillance** on medical devices in your country? *open field* *

a. Name of competent authority in **national language**: *open field*
b. Name of competent authority in **English**: *open field*
c. Can you also provide the official **weblink** of the competent authority? *open field*

16. Are reprocessed single-use devices included in the annual surveillance activity plans? *checkbox: "yes", "I don't know", "no"* *

17. Have you already received reports of serious incidents or Field Safety Corrective Actions (FSCA) on single-use devices? *checkbox: "yes", "I don't know", "no"* *

18. Comments: *"free text; optional"*

Obstacles and challenges regarding reprocessing of single-use devices

19. What are specific challenges for you as a competent authority with the regulation of single-use devices and reprocessing*? open field*
20. What are, in your opinion, obstacles for the reprocessing of single-use devices in Europe?
predefined checkboxes (multiple answers possible): "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "lack of information on the single-use device" "other:___", "none"

21. What are, in your opinion, general enablers for the reprocessing of single-use in Europe?
predefined checkboxes : "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "other:___", "none"

Potential solutions and recommendations

22. Are there currently any discussions and plans at national level that aim to address identified or expected issues and challenges?
Checkbox: "yes", "I don't know", "no"

a. If yes: Please specify main themes of these current discussions. *"studies for feasibility of reprocessing in my country are conducted", "legal amendments are planned to be made", "reprocessing is discussed to be made possible due to special reasons (e.g. shortages)", "other:_____" + option to skip question*

23. Which solutions could be taken to optimise the reprocessing of single-use devices and their use within the EU in your opinion?
predefined rankings : "clear tracking system (e.g. EUDAMED)", "risk management", "regulatory requirements", "identification of suitable products for reprocessing (e.g. EU-wide list)", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "other:_____", "none"

24. Do you have any additional comment, important aspects you would like to mention or general feedback to us? *Open field*

Q4 (CA2): Questionnaire for competent authorities on medical devices of EU-27 Member States, Iceland, Liechtenstein and Norway that do NOT ALLOW reprocessing.

Reprocessing of single-use medical devices

1. Is there a specific reference to the prohibition of reprocessing of single-use products in the national provision(s) of your country? *checkbox: "yes", "no"* *

   If yes, please provide further information: *

   a. Name of national provision(s) in **national language**: *open field*

   b. Name of national provision(s) in **English**: *open field*

   c. Can you also provide the official **weblink** to the national provision(s)? *open field*

   d. When did the national provision(s) **come into force**? *Open field*

2. What are the reasons why your country does not allow reprocessing of single-use devices? *open field* *

3. Does your country refer to any scientific evidence when prohibiting reprocessing of single-use devices? *checkbox: "yes", "no"* *

   a. If yes, please specify this scientific evidence. *Open field*

4. Is there any ongoing discussion on whether your country will allow reprocessing of single-use devices in the future or under certain circumstances (e.g.: shortages, economic situations in hospitals, health crisis)? *predefined checkbox: "yes, it is discussed to be implemented in the future", "maybe under certain circumstances e.g. shortages", ", "I don't know", "no"* *

5. Can reprocessors of SUDs according to MDR Article 17(2) (manufacturers) of other EU-countries make available reprocessed single-use devices in your country? *checkbox: "yes", "no"* *

6. Can reprocessors of SUDs according to MDR Article 17(2) (manufacturers) of non-EU countries make available reprocessed single-use devices in your country? *checkbox: "yes", "no"* *

Obstacles and challenges regarding reprocessing of single-use devices

7. What are, in your opinion, general obstacles for the reprocessing of single-use devices in Europe? *predefined checkboxes (multiple answers possible): "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "lack of information on the single-use device", "other:____", "none"*

8. What are, in your opinion, possible enablers for the reprocessing of single-use devices in Europe? *predefined checkboxes : "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "other:____", "none"*

Potential solutions and recommendations

9. Which solutions could be taken to optimise the reprocessing of single-use devices and their use within the EU in your opinion? *predefined rankings : "clear tracking system (e.g. EUDAMED)", "risk management", regulatory requirements (e.g. European guideline)", "identification of suitable products for reprocessing (e.g. EU-wide list)", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "other:_____", "none"*

10. Do you have any additional comment, important aspects you would like to mention or general feedback to us? *Open field*

Q5 (CA3): Questionnaire for competent authorities on medical devices of EU-27 Member States, Iceland, Liechtenstein and Norway that have not made a decision on allowing reprocessing yet.

Reprocessing of single-use medical devices

1. Why have your country not made a decision regarding the reprocessing of single-use devices yet?
   predefined checkbox: "different opinions of stakeholders"," lack of relevance", "lack of evidence", "complexity of the topic", "bureaucratic efforts", "not a priority topic", "other:___" *

2. Is there a current tendency for prohibiting or allowing reprocessing of single-use devices in your country? *Predefined checkbox There is the tendency to allow reprocessing", "There is the tendency to allow it under certain circumstances e.g. shortages", There is the tendency to prohibit reprocessing", "There is no tendency yet"* *

There is the tendency to allow reprocessing.

b. What is the main reason for potentially allowing reprocessing of single-use devices soon?
   checkboxes: "economic reasons", "environmental reasons", "it is also allowed in other countries", "prevention of shortages", "increase of competition", "other:___"

There is the tendency to allow it under certain circumstances.

c. Please specify these circumstances (e.g. shortages). *Open field*

There is the tendency to prohibit reprocessing.

d. What is the main reason for potentially prohibiting reprocessing of single-use devices soon?
   checkboxes: "safety reasons", "potential health risks", "liability issues", "ethical issues", "lack of evidence", "issues regarding the suitability of devices", "other:___"

There is no tendency yet.

- *If selected: Straight to question 3.*

3. Is there any ongoing discussion on whether your country will allow reprocessing of single-use devices in the future or under certain circumstances (e.g.: shortages, economic situations in hospitals, health crisis)?
   predefined checkbox: "yes, it is discussed to be implemented in the future", "maybe under certain circumstances e.g. shortages", "no" *

4. Are there currently any studies conducted on reprocessing of single-use devices to back up your decision on whether to prohibit or allow reprocessing in your country?
   checkbox: "yes", "I don't know", "no" *

a. If yes, please specify the planned studies. *Open field + option to skip question*

Obstacles and challenges regarding reprocessing of single-use devices

5. What are, in your opinion, general obstacles for the reprocessing of single-use devices in Europe?
   predefined checkboxes (multiple answers possible): "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "lack of information on the single-use device", "other:____", "none"

6. What are, in your opinion, possible enablers for the reprocessing of single-use devices in Europe?
   predefined checkboxes: "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "other:___", "none"

Potential solutions and recommendations

7. Which solutions could be taken to optimise the reprocessing of single-use devices and their use within the EU in your opinion? *predefined rankings : "clear tracking system (e.g. EUDAMED)", "risk management", regulatory requirements (e.g. European guideline)", "identification of suitable products for reprocessing (e.g. EU-wide list)", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "other:_____", "none"*

8. Do you have any additional comment, important aspects you would like to mention or general feedback to us? *open field*

Closing section

We thank you for your participation. We very much appreciate your input. If you have any questions about the survey or our study, please do not hesitate to contact us: mailto:medical.devices@goeg.at.

If you know of any **further (national) contacts or any relevant literature** that could be useful for this study, please feel free to provide contact details.
open field: "further contacts"; open field: "relevant literature"

In addition to this survey, we are conducting **follow-up interviews**. If you are willing to participate, please leave your name and email-address below. We are grateful for your interest and will be happy to contact you for an interview.
open field: ""your company"; "your name and surname"; your e-mail".

Notified bodies

Survey part A

Background

According to Article 17 of Regulation (EU) 2017/745 on medical devices, reprocessing of single-use devices is possible only if permitted by national law.

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via the European Health and Digital Executive Agency (HaDEA) – has commissioned a "**Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market**" (single-use devices and their reprocessing).

The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (now part of S&P Global) and Civic Consulting. The study started in December 2022 and will be running for 14 months (February 2024).

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of single-use devices in Europe will be surveyed.

The study requires us to conduct surveys with **different stakeholder groups**:

1) Notified bodies designated under the MDR who certify reprocessed single-use devices and/or compliance with Regulation (EU) 2020/1207 (CS);
2) Notified bodies designated under the MDR who do NOT certify either reprocessed single-use devices or compliance with Regulation (EU) 2020/1207 (CS);
3) Competent authorities on medical devices of Member States that ALLOW reprocessing;
4) Competent authorities on medical devices of Member States that do NOT ALLOW reprocessing;
5) Competent authorities who have not made a decision regarding reprocessing yet;
6) Manufacturers who reprocess single-use devices;
7) Health institutions, in countries where reprocessing is allowed, that reprocess and/or reuse single-use devices.

In particular, the results of the study shall identify possible proposals for amendments to the MDR with regard to the reprocessing of single-use devices.

The survey results will be exported from the EU survey tool, analysed on an aggregated level in the form of reports and might be published in a dashboard.

Participation in the survey

We collect data/information from different stakeholder groups and tried to keep the workload for completing the surveys to a minimum. Please note that this is a one-time survey. You can download the current version of the survey questionnaire from the menu on your right.

Instructions on how to answer to the survey:

- Navigate through the questionnaire using the arrow buttons at the end of each page.
- To change replies, it is sufficient to go back to the question and modify it.
- A draft of the survey in progress can be saved via the dedicated button on the right end of each page.
- In some questions, additional instructions can be provided in italics (e.g.: *select one option, select all that apply*) – additional instructions will appear in case of errors in the answer (e.g.: "This is not a valid e-mail address.").
- Fields marked with (*) are mandatory. In case of missing mandatory replies, an error message ("This field is required.") in red is displayed on the relevant section of the question when the respondent moves forward in the questionnaire.
- In multiple choice questions, when the option "none" is selected, all the other selected options (if any) will be ignored.
- To submit your replies please be sure to proceed until the very last page by clicking the "**submit**" button at the bottom of said page.
- After submitting the questionnaire, this message will be displayed: "We thank you for your time spent taking this survey. Your response has been recorded". A summary of the replies is provided and can be downloaded in PDF or printed.
- You can find a Glossary of the terms used in this survey at the following link: Glossary

Data protection and consent to participate

Any company specific information (raw data) and personal information of the person responding collected in the survey will be kept confidential. Only aggregated survey outcomes will be published in the data dashboard and analysis reports. We follow the EC privacy statement.

With the submission of your data/information you agree to these terms.

Contact

If you have enquiries, please contact the project coordinator Friederike Windisch (medical.devices@goeg.at).

Please, be aware that only questions applicable to your case will actually be shown to you. The survey self-adapts on the grounds of previous replies. The one included in this file is the full version of the questionnaire: in your case, the survey may be shorter.

About the survey participant

With the submission of your data/information you agree to publication on an aggregated level. *checkbox "I agree"* *

1. Please indicate your NB number in NANDO. *Drop-down field with all NBs designated under the MDR* *
   - Country *drop down – 27 EU-MS; Iceland, Liechtenstein, Norway* *
   - Name of the person completing the survey (optional) *open field*
   - Role (job title / function) of the person completing the survey (optional) *open field*
   - Contact details: phone no (optional) *open field*
   - Contact e-mail address *
2. Do you certify reprocessed single-use devices according to Article 17(2) MDR and/or compliance with the Common Specifications according to Article 17(3) MDR? *Checkbox: "yes", "no" – If yes continue with Q1(NB1); if not continue with Q2(NB2)* *

Survey part B

Q1 (NB1): Questionnaire for notified bodies designated under the MDR who certify reprocessed single-use devices and/or compliance with the CS according to Article 17 MDR

Designation for reprocessing of single-use devices

3. Which designation codes do you apply to certify reprocessed single-use devices according to Article 17(2)? E.g. MDT 2013, product related designation codes, national rules? *Open field* *

4. Which requirements enable you to certify compliance with the Common Specifications according to Article 17(3)? E.g. MDT 2013, other designation codes, national rules? *Open field* *

5. Have you experienced problems during the designation process for reprocessing single-use devices? *checkbox: "yes", "I don't know", "no"* *

   a. If yes: What problems have you experienced? *Open field*

Certification of reprocessed single-use devices

6. Did you receive applications for certification of reprocessed single-use devices according to Article 17(2) MDR and/or compliance with the CS according to Article 17(3) MDR? *checkbox: "yes", "no" – if "yes" continue with Q7– Q12* *
7. How many clients do you have who applied for certification of reprocessed of single-use devices or for compliance with the CS per country (EU-27 MSs, Iceland, Liechtenstein and Norway)?

   ○ For conformity assessment (CE mark) *List of countries*

Country	***Number of clients***
Austria	*No*
Belgium	*No*
Bulgaria	*No*
…	*…*

   ○ For compliance with Common Specifications (CS) *List of countries*

Country	***Number of clients***
Austria	*No*
Belgium	*No*
Bulgaria	*No*
…	*…*

8. How many health institutions are among your clients who applied for certification of compliance with the CS per country (EU-27 MSs, Iceland, Liechtenstein and Norway)?

Country	Number of health institutions
Austria	No
Belgium	No
Bulgaria	No
…	….

9. How many certificates did you issue for reprocessed single-use devices or for compliance with the CS per country (EU-27 MSs, Iceland, Liechtenstein and Norway), since your MDR designation?

- For conformity assessment (CE mark)

Country	Number of certificates issued
Austria	No
Belgium	No
Bulgaria	No
…	….

- For compliance with Common Specifications (CS) *open field*

	Number of certificates issued for health institutions	Number of certificates issued for external reprocessors
Austria	No	No
Belgium	No	No
Bulgaria	No	No
Croatia	No	No
…	…	…

10. What kind of single-use devices do you certify? *

- Cardiovascular
  - Diagnostic electrophysiology (EP) catheters
  - Ultrasound catheters
  - Intra-cardiac echocardiography catheters
  - Intravascular catheters
  - Mapping catheters
  - Coronary sinus catheters
  - EP cables
  - Introducer sheaths
  - Ablation catheter
  - Transseptal needles
  - Radiofrequency catheter
- Arthroscopic/Orthopedic
  - Arthroscopic shavers
  - Arthroscopic wands
  - Bits, burs and blades
  - Shavers
  - External fixation devices and components

- General Surgery
  - Clamps and dissectors
  - Infusion pressure bags
  - Reamers
  - Suture passers
  - Soft tissue ablators
  - Scissor tips
  - Balloon inflation devices
  - Endoscopic accessories
- Laparoscopic
  - Sealers and dividers
  - Ultrasonic scalpels
  - Trocars
  - Laparoscopic instruments including babcocks, dissectors, graspers and scissors
- Non-invasive
  - Blood pressure cuffs and tourniquet cuffs
  - Patient fall alarms
  - Air transfer mattresses / HoverMatts
  - Pneumatic tourniquet cuffs
  - Infusor bags
  - Tourniquets
  - EKG and ECG leads and cables
  - Femoral compression devices
  - Pulse oximeter sensors
  - Sequential compression devices / DVT sleeves
- Others *open field*
- I don't know

11. Which risk classes are among the certified SUD? *Please select all that apply.* *
    - Class I
    - Class Is
    - Class Im
    - Class IIa
    - Class IIb
    - Class III
    - Not Applicable *(if selected, all the other options will be ignored)*

Challenges and opportunities regarding reprocessing of single-use devices

12. What are specific challenges for <u>you as a notified body</u> to certify reprocessed single-use devices or compliance with the CS? *Open field*

13. What are, in your opinion, <u>general obstacles</u> for the reprocessing of single-use devices in the European Union?
    Predefined checkboxes (multiple answers possible): "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "other:___", "none"

14. What are, in your opinion, general <u>opportunities</u> regarding the reprocessing of single-use devices in the EU?
    Predefined checkboxes: "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "other:___", "none"

Potential actions and recommendations

15. Are there currently any discussions and plans <u>at your notified body</u> that aim to address identified or expected issues and challenges? *Checkbox: "yes", "I don't know", "no"*
    a. If yes: Please specify possible actions. *Open field*

16. Which actions could be taken to optimise the reprocessing of single-use devices and their use within the EU in your opinion?
    predefined rankings : "clear tracking system (e.g. EUDAMED)", "risk management", regulatory requirements (e.g. European

guideline)", "identification of suitable products for reprocessing (e.g. EU-wide list)", "clarification on designation codes on NANDO", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "other:_____", "none"

17. Do you have any additional comment, important aspects you would like to mention or general feedback to us?
open field (+option to leave it blank)

Q2 (NB2): Questionnaire for notified bodies designated under the MDR who do NOT certify reprocessed single-use devices and/or compliance with the CS according to Article 17 MDR

Reprocessing of single-use medical devices

3. What are the reasons why your NB does not certify reprocessed single-use devices or compliance with the CS? *open field* *

Challenges and opportunities regarding reprocessing of single-use devices

4. What are specific challenges for you as a notified body for applying for designation on reprocessing single-use devices? *open field*

5. What are, in your opinion, general obstacles for the reprocessing of single-use devices in the European Union?
Predefined checkboxes (multiple answers possible): "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "other:___", "none"

6. What are, in your opinion, general opportunities regarding the reprocessing of single-use devices in the European Union?
Predefined checkboxes: "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "other:___", "none"

Potential actions and recommendations

7. Are there currently any discussions and plans at your notified body that aim to address identified or expected issues and challenges? *Checkbox: "yes", "I don't know", "no"*
   b. If yes: Please specify possible actions. *Open field*

8. Which actions could be taken to optimise the reprocessing of single-use devices and their use within the EU in your opinion?
predefined rankings : "clear tracking system (e.g. EUDAMED)", "risk management", regulatory requirements (e.g. European guideline)", "identification of suitable products for reprocessing (e.g. EU-wide list)", "clarification on designation codes on NANDO", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "other:_____", "none"

9. Do you have any additional comment, important aspects you would like to mention or general feedback to us?
open field (+option to leave it blank)

Closing

We thank you for your participation. We very much appreciate your input. If you have any questions about the survey or our study, please do not hesitate to contact us: mailto:medical.devices@goeg.at:

If you know of any **further (national) contacts or any relevant literature** that could be useful for this study, please feel free to provide contact details. *open field: "further contacts"; open field: "relevant literature"*

In addition to this survey, we are conducting **follow-up interviews**. If you are willing to participate, please leave your name and email-address below. We are grateful for your interest and will be happy to contact you for an interview. *open field: "contact details for follow-up interviews"*

Manufacturers that reprocess SUDs

Survey part A

Background

According to Article 17 of Regulation (EU) 2017/745 on medical devices, reprocessing of single-use devices is possible only if permitted by national law.

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The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of single-use devices in Europe will be surveyed.

The study requires us to conduct surveys with **different stakeholder groups**:

1) Notified bodies designated under the MDR who certify reprocessed single-use devices and/or compliance with Regulation (EU) 2020/1207 (CS);
2) Notified bodies designated under the MDR who do NOT certify either reprocessed single-use devices or compliance with Regulation (EU) 2020/1207 (CS);
3) Competent authorities on medical devices of Member States that ALLOW reprocessing;
4) Competent authorities on medical devices of Member States that do NOT ALLOW reprocessing;
5) Competent authorities who have not made a decision regarding reprocessing yet;
6) Manufacturers who reprocess single-use devices;
7) Health institutions, in countries where reprocessing is allowed, that reprocess and/or reuse single-use devices;

In particular, the results of the study shall identify possible proposals for amendments to the MDR with regard to the reprocessing of single-use devices.

The survey results will be exported from the EU survey tool, analysed on an aggregated level in the form of reports and might be published in a dashboard.

Participation in the survey

We collect data/information from different stakeholder groups and tried to keep the workload for completing the surveys to a minimum. Please note that this is a one-time survey. You can download the current version of the survey questionnaire from the menu on your right.

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- Fields marked with (*) are mandatory. In case of missing mandatory replies, an error message ("This field is required.") in red is displayed on the relevant section of the question when the respondent moves forward in the questionnaire.
- In multiple choice questions, when the option "none" is selected, all the other selected options (if any) will be ignored.

- To submit your replies please be sure to proceed until the very last page by clicking the "**submit**" button at the bottom of said page.
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With the submission of your data/information you agree to these terms.

Contact

If you have enquiries, please contact the project coordinator Friederike Windisch (medical.devices@goeg.at).

Please, be aware that only questions applicable to your case will actually be shown to you. The survey self-adapts on the grounds of previous replies. The one included in this file is the full version of the questionnaire: in your case, the survey may be shorter.

About the survey participant

» With the submission of your data/information you agree to publication on an aggregated level. *checkbox "I agree"* *
» Country *drop down – 27 EU-MS; Iceland, Liechtenstein, Norway* *
» Institution *open field* *
» Name of the person completing the survey (optional) *open field*
» Role (job title / function) of the person completing the survey (optional) *open field*
» Contact details: phone no (optional) *open field*
» Contact e-mail address*
» Indication of the stakeholder group you belong to:*
  ○ Manufacturer who reprocess single-use devices (Q6-MF1)
  ○ Manufacturer who DOES NOT reprocess single-use devices (end of the survey)

Survey part B
Q6 (MF1): Questionnaire for Manufacturers that reprocess single-use devices

About your company

1. Is your company a small and medium-sized enterprise[12] (SME)? *Checkbox: "yes", "no"* *

2. Is your company solely working on reprocessing of single-use devices or also on multiple use devices? *Checkbox: "single-use only", "single- and multiple-use"* *

[12] **Definition SME:** The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ **fewer than 250 persons** and which have an **annual turnover not exceeding EUR 50 million**, and/or an **annual balance sheet total not exceeding EUR 43 million**. (Source: extract of Article 2 of the annex to Recommendation 2003/361/EC.)

3. Do you act as a manufacturer of CE-marked products and/or offer reprocessing as service complying to the Regulation (EU) 2020/1207(CS)? *Checkbox: "yes – both", "only as manufacturer; CE mark", "only reprocessing as service (CS)"* *

4. In which countries in the European market are your reprocessed single-use devices made available? Checkbox: all EU countries plus Iceland, Liechtenstein, and Norway *

5. Do you know of any national provisions in EU Member States regarding the reprocessing of single-use devices? *Checkbox "yes", "no"* *

   a. If yes, please indicate the country and the link to the national provision. Open field

6. Does your company transfer reprocessed single-use devices to third countries outside of the EU?
   checkbox: "yes, to other European countries (non-EU)", "yes, to other European countries (non-EU) and outside of Europe", "no" *

7. How many manufacturers (based in the EU) would you estimate reprocess single-use devices?
   predefined rankings: "1-5 manufacturers", "6-10 manufacturers", "11-20", "more than 20" *

Reprocessing of single-use devices

8. Which kinds of single-use devices do you reprocess? *Predefined ranking (MD types) plus "other option"* *

   a. Cardiovascular

   - Diagnostic electrophysiology (EP) catheters
   - Ultrasound catheters
   - Intra-cardiac echocardiography catheters
   - Intravascular catheters
   - Mapping catheters
   - Coronary sinus catheters
   - EP cables
   - Introducer sheaths
   - Ablation catheter
   - Transseptal needles
   - Radiofrequency catheter

   b. Arthroscopic/Orthopedic

   - Arthroscopic shavers
   - Arthroscopic wands
   - Bits, burs and blades
   - Shavers
   - External fixation devices and components

   c. General Surgery

   - Clamps and dissectors
   - Infusion pressure bags
   - Reamers
   - Suture passers
   - Soft tissue ablators
   - Scissor tips
   - Balloon inflation devices
   - Endoscopic accessories

   d. Laparoscopic

   - Sealers and dividers
   - Ultrasonic scalpels
   - Trocars
   - Laparoscopic instruments including babcocks, dissectors, graspers and scissors

   e. Non-invasive

   - Blood pressure cuffs and tourniquet cuffs
   - Patient fall alarms
   - Air transfer mattresses / HoverMatts
   - Pneumatic tourniquet cuffs
   - Infusor bags

- Tourniquets
- EKG and ECG leads and cables
- Femoral compression devices
- Pulse oximeter sensors
- Sequential compression devices / DVT sleeves

f. Others *open field*

9. Which risk classes are included in your portfolio and to which extent? *Checkbox for MD risk classes plus indication of percentage of the product portfolio* *

a. Class I: *open field for percentage*

b. Class Is *open field for percentage*

c. Class Im *open field for percentage*

d. Class IIa: *open field for percentage*

e. Class IIb: *open field for percentage*

f. Class III: *open field for percentage*

10. What were the quantities of single-use devices that were reprocessed by your company in the last year? *Open field* *

11. Which examples of single-use devices are considered safe to be reprocessed according to latest scientific evidence? *Open field* *

a. If available, please indicate the latest scientific evidence, any studies, surveys or data that support this? *Open field*

12. Which examples of single-use devices are <u>not</u> considered safe to be reprocessed (according to latest scientific evidence)? *Open field* *

a. If available, please indicate any studies, surveys or data that support this? *Open field*

Certification of reprocessing of single-use devices

13. Have you already submitted an application for the certification of a reprocessed single-use device to a notified body? *Checkbox: "yes", "no"* *

a. If no, when do you plan to submit a certification application for a reprocessed single-use device to a notified body? *Drop down*

- in less than 3 months
- within the next 3–5 months
- within the next 6–12 months
- within the next 13–18 months
- within the next 19–24 months
- not at all

b. If yes, when did you receive or do you expect the first certificate for the reprocessed single-use device? (Please insert the date in the format mm/yyyy) *Open field (date entry)*

14. What is the (expected) time to obtain a new EC certificate (from written agreement signed to issuance) under MDR or for compliance with the Regulation (EU) 2020/1207 (CS) from your notified body? *Time periods* *

Time to certification for reprocessed single-use devices that need only QMS certificates

- less than 6 months
- 6–12 months
- 13–18 months

- 19–24 months
- more than 24 months
- I don't know

Time to certification for reprocessed single-use devices that need QMS and product certificates

- less than 6 months
- 6–12 months
- 13–18 months
- 19–24 months
- more than 24 months
- I don't know

Time to certification for compliance with the CS

- less than 6 months
- 6–12 months
- 13–18 months
- 19–24 months
- more than 24 months
- I don't know

15. Any specific issues in relation to certification of reprocessing of SUD? *Open field*

Challenges and opportunities regarding reprocessing of single-use devices

16. What are specific challenges for <u>you as company</u> to reprocess single-use devices?
open field

17. What are, in your opinion, <u>general obstacles</u> for the reprocessing of single-use devices in the European Union?
predefined checkboxes (multiple answers possible): "fragmented implementation of Article 17", "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "other:____", "none"

18. What are, in your opinion, <u>general opportunities</u> regarding the reprocessing of single-use devices in the European Union?
predefined checkboxes : "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "other:____", "none"

Potential actions and recommendations

19. Are there currently any discussions and plans <u>in your company</u> that aim to address identified or expected issues and challenges?
Checkbox: "yes", "I don't know", "no"

a. If yes: Please specify possible actions. *Open field*

20. Which actions could be taken to optimise the reprocessing of single-use devices and their use <u>within the EU</u> in your opinion?
predefined rankings : "clear tracking system (e.g. EUDAMED)", "risk management", regulatory requirements (e.g. European guideline)", "identification of suitable products for reprocessing (e.g. EU-wide list)", "clarification on designation codes on NANDO", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "other:_____", "none"

21. Do you have any additional comment, important aspects you would like to mention or general feedback to us?
open field (+option to leave it blank)

Closing

We thank you for your participation. We very much appreciate your input. If you have any questions about the survey or our study, please do not hesitate to contact us: mailto:medical.devices@goeg.at.

If you know of any **further (national) contacts or any relevant literature** that could be useful for this study, please feel free to provide contact details.
open field: "further contacts"; open field: "relevant literature"

In addition to this survey, we are conducting **follow-up interviews**. If you are willing to participate, please leave your name and email-address below. We are grateful for your interest and will be happy to contact you for an interview.
open field: "contact details for follow-up interviews"

Health institutions

Survey part A

Background

According to Article 17 of Regulation (EU) 2017/745 on medical devices, reprocessing of single-use devices is possible only if permitted by national law.

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via the European Health and Digital Executive Agency (HaDEA) – has commissioned a "**Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market**" (single-use devices and their reprocessing).

The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (now part of S&P Global) and Civic Consulting. The study started in December 2022 and will be running for 14 months (February 2024).

The general objective of the study is to **evaluate how the provisions established in Article 17 of Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and **how such provisions operate**. For this purpose, the current market situation for reprocessing and reuse of single-use devices in Europe will be surveyed.

The study requires us to conduct surveys with **different stakeholder groups**:

1) Notified bodies designated under the MDR who certify reprocessed single-use devices and/or compliance with Regulation (EU) 2020/1207 (CS);
2) Notified bodies designated under the MDR who do NOT certify either reprocessed single-use devices or compliance with Regulation (EU) 2020/1207 (CS);
3) Competent authorities on medical devices of Member States that ALLOW reprocessing;
4) Competent authorities on medical devices of Member States that do NOT ALLOW reprocessing;
5) Competent authorities who have not made a decision regarding reprocessing yet;
6) Manufacturers who reprocess single-use devices;
7) Health institutions, in countries where reprocessing is allowed, that reprocess and/or reuse single-use devices.

In particular, the results of the study shall identify possible proposals for amendments to the MDR with regard to the reprocessing of single-use devices.

The survey results will be exported from the EU survey tool, analysed on an aggregated level in the form of reports and might be published in a dashboard.

Participation in the survey

We collect data/information from different stakeholder groups and tried to keep the workload for completing the surveys to a minimum. Please note that this is a one-time survey. You can download the current version of the survey questionnaire from the menu on your right.

Instructions on how to answer to the survey:

» Navigate through the questionnaire using the arrow buttons at the end of each page.
» To change replies, it is sufficient to go back to the question and modify it.
» A draft of the survey in progress can be saved via the dedicated button on the right end of each page.
» In some questions, additional instructions can be provided in italics (e.g.: *select one option*, *select all that apply*) – additional instructions will appear in case of errors in the answer (e.g.: "*This is not a valid e-mail address*.")
» Fields marked with (*) are mandatory. In case of missing mandatory replies, an error message ("*This field is required*.") in red is displayed on the relevant section of the question when the respondent moves forward in the questionnaire.
» In multiple choice questions, when the option "none" is selected, all the other selected options (if any) will be ignored.
» To submit your replies please be sure to proceed until the very last page by clicking the "submit" button at the bottom of said page.
» After submitting the questionnaire, this message will be displayed: "We thank you for your time spent taking this survey. Your response has been recorded". A summary of the replies is provided and can be downloaded in PDF or printed.
» You can find a Glossary of the terms used in this survey at the following link: link to glossary

Data protection and consent to participate

Any company specific information (raw data) and personal information of the person responding collected in the survey will be kept confidential. Only aggregated survey outcomes will be published in the data dashboard and analysis reports. We follow the EC privacy statement.

With the submission of your data/information you agree to these terms.

Contact

If you have enquiries, please contact the project coordinator Friederike Windisch (medical.devices@goeg.at).

Please, be aware that only questions applicable to your case will actually be shown to you. The survey self-adapts on the grounds of previous replies. The one included in this file is the full version of the questionnaire: in your case, the survey may be shorter.

About the survey participant

» With the submission of your data/information you agree to publication on an aggregated level. *checkbox "I agree"* *
» Country *drop down – 27 EU-MS; Iceland, Liechtenstein, Norway* *
» Institution *open field*
» Name of the person completing the survey (optional) *open field*
» Role (job title / function) of the person completing the survey (optional) *open field*
» Contact details: phone no (optional) *open field*
» Contact e-mail address *
» Indication of the stakeholder group you belong to: *single-choice (trigger for the right questionnaire)* *

- ○ Health institutions in countries where reprocessing of single-use devices is allowed (Q7-HI1)
- ○ Health institutions in countries where reprocessing of single-use devices is not allowed (end of the survey)

Survey part B:

Q7 (HI1): Questionnaire for health institutions in countries where reprocessing of single-use devices is allowed

Introductory questions to all health institutions

1. Do you reprocess (or plan to reprocess) single-use devices at your health institution (in-house)? *Checkboxes: "Yes, we are reprocessing or planning to reprocess single-use devices", "No, we do not reprocess or plan to reprocess single-use devices"* *

   a. If yes, are you reprocessing or planning to reprocess single-use devices at your health institution (in-house)? *Checkboxes: "We are currently reprocessing single-use devices", "We are planning to reprocess single-use devices"*

2. Are you reusing purchased single-use devices at your health institution? *Checkboxes: "yes", "no"* *

   a. If 1+2= yes: questions for HI that reprocess SUDs + reuse SUDs

   b. If only 2=yes: questions for HI that reuse reprocessed SUDs

   c. If 1+2=no: Part 3

Part 1 (health institutions that reprocess or plan to reprocess SUD)

Legal provisions for reprocessing SUD in your country

3. Do you know of any national provision related to the reprocessing of single-use devices for health institutions in your country? *Checkboxes: "yes", "no"* *

   a. If yes: Please specify the national provision: *open field*

   b. If yes: Are there currently any prohibition or restrictions on the **types of single-use devices** that can be reprocessed in your institution? *Checkboxes: "yes", "I don't know", "no"* *

Reprocessing of single-use devices

4. Why have you decided to reprocess or plan to reprocess single-use devices in your health institution? *
   Predefined checkboxes: "economic reasons", "environmental aspects", "legal allowance", "special circumstances e.g. shortages, pandemic", "reprocessing was already established in our institution", "other:____", "I don't know"

5. Which kinds of single-use devices do you reprocess or plan to reprocess? *

   a. Cardiovascular

      - Diagnostic electrophysiology (EP) catheters
      - Ultrasound catheters
      - Intra-cardiac echocardiography catheters
      - Intravascular catheters
      - Mapping catheters
      - Coronary sinus catheters
      - EP cables
      - Introducer sheaths
      - Ablation catheter
      - Transseptal needles
      - Radiofrequency catheter

   b. Arthroscopic/Orthopedic

- Arthroscopic shavers
- Arthroscopic wands
- Bits, burs and blades
- Shavers
- External fixation devices and components

c. General Surgery

- Clamps and dissectors
- Infusion pressure bags
- Reamers
- Suture passers
- Soft tissue ablators
- Scissor tips
- Balloon inflation devices
- Endoscopic accessories

d. Laparoscopic

- Sealers and dividers
- Ultrasonic scalpels
- Trocars
- Laparoscopic instruments including babcocks, dissectors, graspers and scissors

e. Non-invasive

- Blood pressure cuffs and tourniquet cuffs
- Patient fall alarms
- Air transfer mattresses / HoverMatts
- Pneumatic tourniquet cuffs
- Infusor bags
- Tourniquets
- EKG and ECG leads and cables
- Femoral compression devices
- Pulse oximeter sensors
- Sequential compression devices / DVT sleeves

f. Others *open field*

g. I don't know

6. Which risk classes are / will be included in your portfolio and to which extent? *Checkbox for MD risk classes plus indication of percentage of the product portfolio (if you cannot indicate the extent, please state "n/a".* *

a. Class I: *open field for percentage*

b. Class IIa: *open field for percentage*

c. Class IIb: *open field for percentage*

d. Class III: *open field for percentage*

7. Do you (plan to) also outsource reprocessing of single-use devices to external reprocessors? *Checkboxes: "yes", "no"* *

8. Do you face any challenges regarding the implementation of the Common Specifications or national provisions – in relation to: *

a. Risk management system *checkbox: "yes", "no"*

b. Validation of procedures for the entire process *checkbox: "yes", "no"*

c. Product release and performance testing *checkbox: "yes", "no"*

d. Quality management system *checkbox: "yes", "no"*

e. Reporting of incidents *checkbox: "yes", "no"*

f. Traceability of reprocessed devices? *Checkbox: "yes", "no"*

g. Other factors: please specify *"open field"*

➔ If yes to any of the question above, please specify which challenges: *"open field"*

9. Do you provide information to patients on the use of reprocessed devices within your health institution? *Checkbox: "yes", "not yet", "no"* *

   a. If yes, how do you provide information? *Checkboxes "in general, on the website"; "individual information to the patient", "other: _____"*

Certification of reprocessing of single-use devices

10. Do you have a certificate of compliance with Regulation (EU) 2020/1207 (CS)? *checkbox: "yes", "no"* *

    a) If yes: Please specify the identification number of the notified body. *Drop down field (all NBs designated under the MDR)* *

    b) If yes: Could you please briefly describe the certification process by your notified body? *Open field*

    c) If yes: Have there been any specific challenges in certification of reprocessing of SUD? *Open field*

    d) If no: Do you have a written agreement with a notified body for the certification of compliance with Regulation (EU) 2020/1207 (CS)? *checkbox: "yes", "no"* *

11. What is the time (expected) to obtain a certificate (from written agreement signed to issuance) for compliance with Regulation (EU) 2020/1207 (CS) from your notified body? *

    a. less than 6 months

    b. 6–12 months

    c. 13–18 months

    d. 19–24 months

    e. more than 24 months

    f. I don't know

Challenges and opportunities regarding reprocessing of single-use devices

12. What are specific challenges for you as health institution to (plan to) reprocess single-use devices? *Open field*

13. What are, in your opinion, general obstacles for the reprocessing of single-use devices in the European Union?
predefined checkboxes (multiple answers possible): "fragmented implementation of Article 17", "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "finding a notified body", "other: ____", "none"

14. What are, in your opinion, general opportunities regarding the reprocessing of single-use devices for health institutions in the European Union?
predefined checkboxes : "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "changes to devices through reprocessing to the benefit of the patient", "other:____", "none"

Potential actions and recommendations

15. Are there currently any discussions and plans at your institution that aim to address identified challenges regarding the reprocessing of single-use devices? *
checkbox: "yes", "I don't know", "no"

    a. If yes: Please specify potential actions. *open field*

16. Which actions could be taken to optimise the reprocessing of single-use devices and their use within the EU in your opinion? *
predefined rankings: "clear tracking system (e.g. EUDAMED)", "risk management", regulatory requirements (e.g. European guideline)", "identification of suitable products for reprocessing (e.g. EU-wide list)", "clarification on designation codes on NANDO", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "increase the number of notified bodies certifying reprocessing of single-use devices", "other:_____", "none"

Part 2 (health institutions that reuse purchased single-use devices)

Legal provisions for reusing reprocessed SUD in your country

1. Do you know of any national provision related to the reusing of single-use devices for health institutions in your country? *checkboxes: "yes", "no"* *

   a. If yes: Please specify the national provision: *open field*

Reusing of single-use devices in your institution

2. Where do you get the reprocessed single-use devices from? *Checkboxes [multiple-choice]: "reprocessors that assume the manufacturer's obligations", "other: _____"* *

3. Which kinds of single-use devices do you reuse? *checkboxes*

   a. Cardiovascular

   - Diagnostic electrophysiology (EP) catheters
   - Ultrasound catheters
   - Intra-cardiac echocardiography catheters
   - Intravascular catheters
   - Mapping catheters
   - Coronary sinus catheters
   - EP cables
   - Introducer sheaths
   - Ablation catheter
   - Transseptal needles
   - Radiofrequency catheter

   b. Arthroscopic/Orthopedic

   - Arthroscopic shavers
   - Arthroscopic wands
   - Bits, burs and blades
   - Shavers
   - External fixation devices and components

   c. General Surgery

   - Clamps and dissectors
   - Infusion pressure bags
   - Reamers
   - Suture passers
   - Soft tissue ablators
   - Scissor tips
   - Balloon inflation devices
   - Endoscopic accessories

   d. Laparoscopic

   - Sealers and dividers
   - Ultrasonic scalpels
   - Trocars
   - Laparoscopic instruments including babcocks, dissectors, graspers and scissors

   e. Non-invasive

   - Blood pressure cuffs and tourniquet cuffs
   - Patient fall alarms
   - Air transfer mattresses / HoverMatts
   - Pneumatic tourniquet cuffs
   - Infusor bags
   - Tourniquets
   - EKG and ECG leads and cables

- Femoral compression devices
- Pulse oximeter sensors
- Sequential compression devices / DVT sleeves

f. Others *open field*

2. Why have you decided to reuse reprocessed single-use devices in your health institution? *
checkboxes: "economic reasons", "environmental aspects", "legal allowance", "special circumstances e.g. shortages, pandemic", "reusing reprocessed single-use device was already established in our institution", "other:____", "I don't know"

3. Do you provide information to patients on the use of reprocessed devices within your health institution? *checkbox: "yes", "no"* *

a. If yes, how do you provide information? *Checkboxes "in general, on the website"; "individual information to the patient", "other: _____"*

Challenges and opportunities regarding reusing reprocessed single-use devices

4. What are specific challenges for you as health institution to reuse reprocessed single-use devices? *open field*

5. What are, in your opinion, general obstacles for the reuse of reprocessed single-use devices in the European Union?
predefined checkboxes (multiple answers possible): "fragmented implementation of Article 17", "potential health risks", "changes to devices through reprocessing (e.g. impairment)", "issues of liability", "ethical considerations", "lack of evidence", "differences in the suitability of devices", "practice of manufacturers (e.g. upclassifying device risk)", "other:____", "none"

6. What are, in your opinion, general enablers for the reuse of reprocessed single-use devices?
predefined checkboxes : "cost savings", "environmental benefit", "solution for shortages", "increase in competition", "other:____", "none"

Potential actions and recommendations

7. Are there currently any discussions and plans at your institution that aim to address identified challenges regarding the reuse of reprocessed single-use devices?*
checkbox: "yes", "I don't know", "no"

a. If yes: Please specify potential actions. *open field*

8. Which actions could be taken to increase the reuse of reprocessed single-use devices within the EU in your opinion? *
predefined rankings: "clear tracking system (e.g. EUDAMED)", "risk management", regulatory requirements (e.g. European guideline)", "identification of suitable products for reprocessing (e.g. EU-wide list)", "clarification on designation codes on NANDO", "amendments in the MDR", "extended producer responsibility", "better staff education on reprocessing", "other:_____", "none"

9. Do you have any additional comment, important aspects you would like to mention or general feedback to us? *open field*

Part 3 (health institutions that do not reprocess or plan to reprocess SUD)

Reprocessing of single-use medical devices

10. What are the reasons why your health institution does not reprocess single-use devices? *open field**

11. Do you have any additional comment or important aspects you would like to mention or general feedback to us?
open field (+option to leave it blank)

Closing section

We thank you for your participation. We very much appreciate your input. If you have any questions about the survey or our study, please do not hesitate to contact us: mailto:medical.devices@goeg.at

If you know of any **further (national) contacts or any relevant literature** that could be useful for this study, please feel free to provide contact details.
open field: "further contacts"; open field: "relevant literature"

In addition to this survey, we are conducting **follow-up interviews**. If you are willing to participate, please leave your name and email-address below. We are grateful for your interest and will be happy to contact you for an interview.
open field: ""your institutions"; "your name and surname"; your e-mail".

Annex VIII: Follow-up e-mails sent to NBs and CAs

Table 19: Follow-up emails sent to NBs and CAs

Stakeholder	E-mail text
CAs	**Have there been any changes/plans since completing the survey?** Since the study is entering a new phase of *data validation and update*, we are contacting you again to ask whether key changes have already occurred / are planned in your Member State in the implementation of Article 17 of Regulation (EU) 2017/745 (MDR) on the reprocessing of single-use devices, in the time between completing the survey until the end of this year. In particular: • Has any change occurred in the national legislation allowing/not allowing reprocessing of single use devices since completing the survey? [*yes/no*] o If yes, please specify. • Are any (other) changes expected by the end of this year (up to 31 December 2023)? [*yes/no*] If yes, please specify.
NBs	**Have there been any changes/plans since completing the survey?** Since the study is entering a new phase of *data validation and update*, we are contacting you again to ask whether key changes have already occurred / are planned in your Member State in the implementation of Article 17 of Regulation (EU) 2017/745 (MDR) on the reprocessing of single-use devices, in the time between completing the survey until the end of this year. In particular: • Do you now certify reprocessed single-use devices according to Article 17(2) MDR and/or compliance with the Common Specifications according to Article 17(3) MDR? [yes/no] o If yes, which designation codes do you apply to certify reprocessed single-use devices according to Article 17(2)? o If no, are there plans to certify reprocessed single-use devices? • Are any changes expected by the end of this year (up to 31 December 2023)? [yes/no] o If yes, please specify.

Source: the contractor

Annex IX: List of indicators

Table 20: Overview of process and outcome indicators

Indicators	Details			
Dashboard (scope)				
Indicators	A variety of process and outcome indicators was included in the dashboard for this study (see below for details on indicators).			
Stakeholders	Information collected from four stakeholder groups was included in the dashboard: • Competent authorities (CAs) • Notified bodies (NBs) • Manufacturers (MFs) • Health Institutions (HIs)			
SUDs	The information presented in the dashboard covers SUDs available on the EU market and belonging to all types and risk classes (if reprocessed). Reusable devices (such as surgical instruments, arthroscopic instruments, pelvis copes) are not considered.			
Surveys	Two survey rounds (initial survey and survey update) were performed for all stakeholder groups except for HIs (initial survey round only, as no changes expected).			
Process indicators				
Initial survey				
	CAs	**NBs**	**MFs**	**HIs**
Number of entities contacted	CAs of 30 countries	38	No information available (dissemination via national associations)	
Number of replies	35 CAs of 30 countries	38	2	46, of which 27 (59%) had to be excluded → 19 valid replies
Participation rate in %	100% of the countries	100%	No information available (dissemination via national associations)	
Survey update				
Number of entities contacted	CAs of 30 countries	42 (incl. newly designated NBs since the survey)	2	No survey update was performed for HIs (no changes were expected)
Number of replies	32 CAs of 27 countries	35	2	
Participation rate in %	90% of the countries	83%	100%	

Indicators	Details
Outcome indicators	

Current SUD reprocessing situation quantification[1]	**CAs**
	• Number of Member States that permit/prohibit the reprocessing of SUDs on the national territory:
	  ○ Reprocessing allowed: 10
	  ▪ MF obligations: country decided to apply Article 17(2) MDR: 7
	  ▪ Common specifications: country decided not to apply all of the rules laid down in Article 17(2) MDR: 5
	  ▪ Outsourcing: country decided to apply Article 17(3) MDR: 6
	  ▪ Patient information: country requires HIs to provide information to patients: 3
	  ▪ Restrictions and prohibitions: country imposed restrictions and prohibitions: 7
	  ○ Reprocessing prohibited: 17
	  ○ No decision taken yet: 3
	• Number of Member States transferring SUDs to other MS or third countries: n.a.
	
	NBs
	• NBs certifying reprocessed SUDs and reprocessing SUDs: 6
	• NBs not certifying reprocessed SUDs and reprocessing SUDs: 32
	• Number of clients having applied for conformity assessment (CE mark) for reprocessed SUDs: 2
	• Number of clients having applied for compliance with the CS: 1
	• Number of certificates issued by NBs for reprocessed SUDs or compliance with the CS: 0
	
	MFs
	• Manufacturers who reprocess SUDs: 2
	• Manufacturers of CE-marked products and offer reprocessing as service complying to the Regulation (EU) 2020/1207(CS): 1
	• Manufacturers only offering reprocessing as service complying to the Regulation (EU) 2020/1207(CS): 1
	• Total number of SUDs that were reprocessed in 2022: 535000
	
	HIs
	• Number of HIs reprocessing and reusing SUDs according to the CS: 9 (4 reprocess and reuse SUDs, 5 plan to reprocess SUDs)
	• Number of certificates of compliance with Regulation (EU) 2020/1207 (CS) by HIs: 0
	• Number of written agreements with a notified body for the certification of compliance with Regulation (EU) 2020/1207 (CS): 0
	• Number of external reprocessors, if applicable performing reprocessing of SUDs upon request of a HI: 2

[1] The initial performance indicators as developed at the beginning of the study were adapted according to the approved survey structure and dashboard.

Source: the contractor

Annex X: Dashboard

Figure 7: Dashboard: Home

Figure 8: Dashboard: About

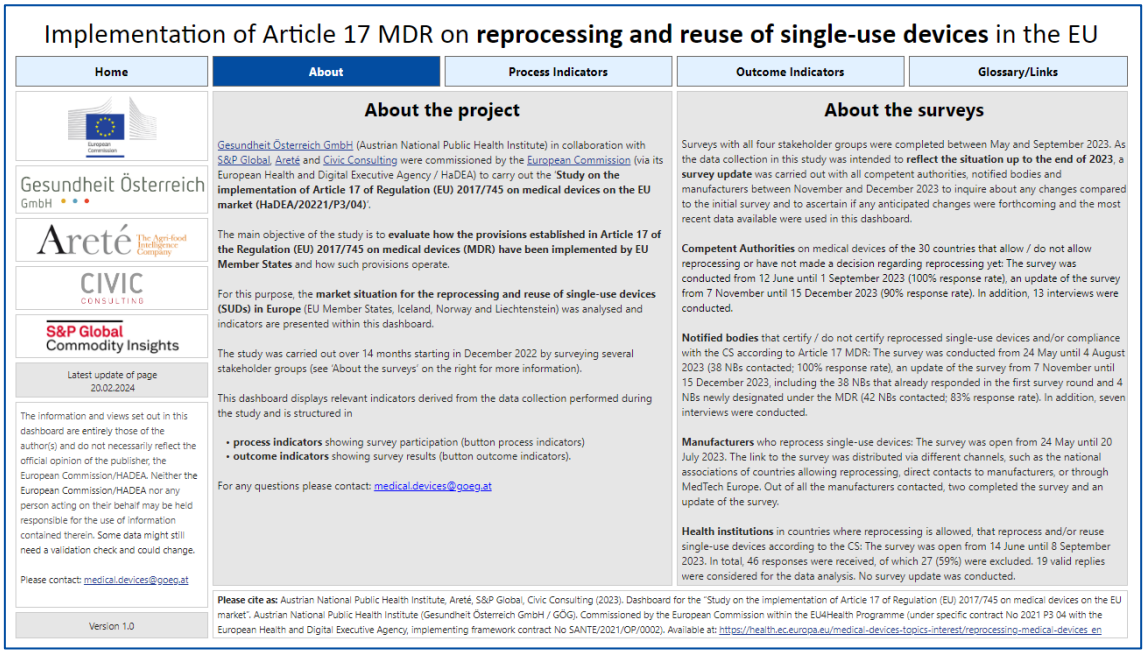


Figure 9: Dashboard: Process indicators

Figure 10: Dashboard: Outcome indicators

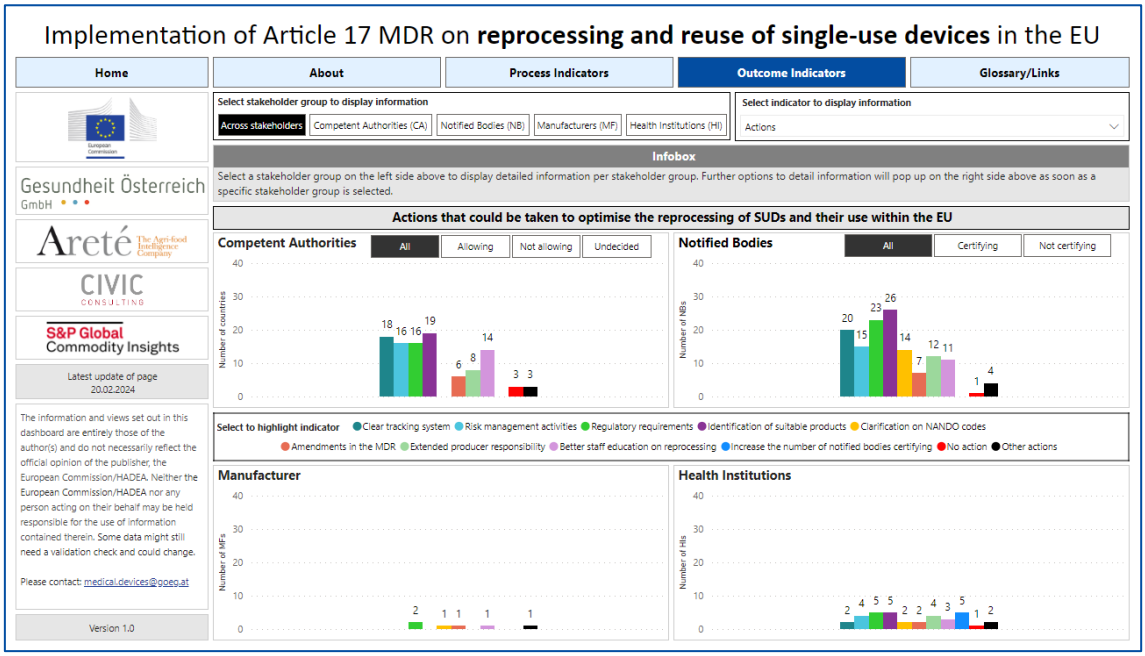
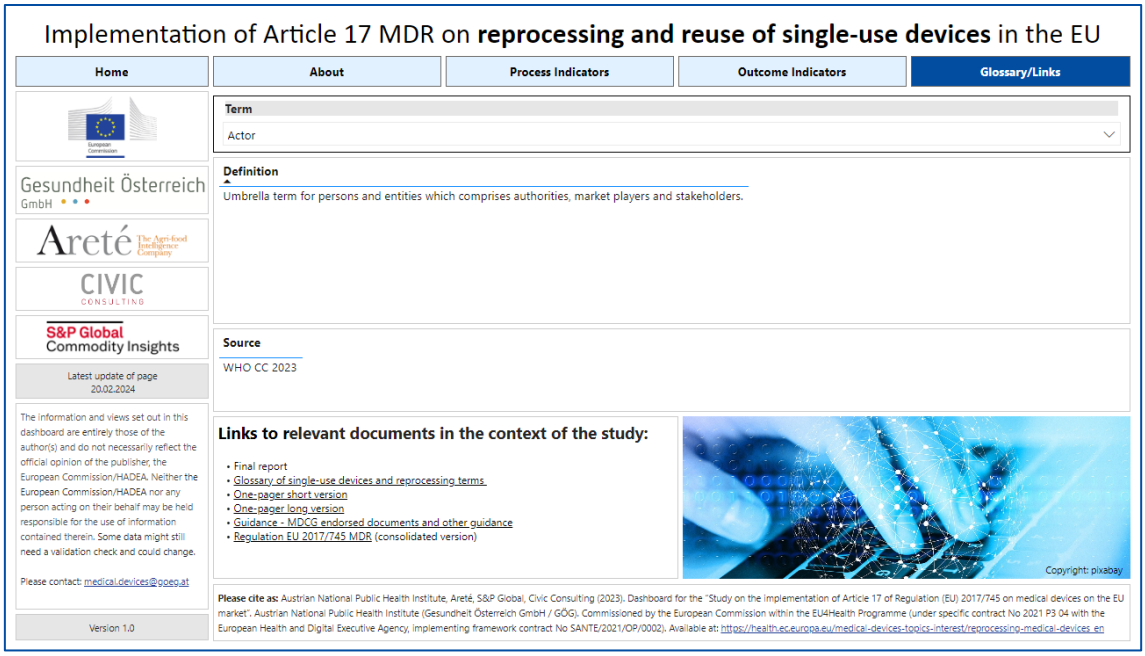


Figure 11: Dashboard: Glossary/Links



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