

# Survey on costs, timelines, and procedures for the reprocessing of single-use devices (SUDs) and the reuse of surgical instruments in the European Union

Fields marked with \* are mandatory.

## About the study

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The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - has commissioned the study **Analyses on markets of medical devices and of medicinal products – MedPro II**.

Contracted to a consortium led by Technopolis, in collaboration with the Austrian National Public Health Institute (Gesundheit Österreich Beratungs GmbH/GÖ B), IQVIA and PredictBy, the project started in September 2025 and will end in March 2026.

Sub-Task 1.4, led by the GÖ B in collaboration with RAND Europe and Milieu Consulting SRL, is **an analysis on the impact of changes on requirements for the reprocessing of devices**.

The main objective of this analysis is to investigate the reprocessing of single use devices (SUDs) conducted in accordance with Article 17 of MDR, and to compare costs, timelines and procedures required for the reprocessing of SUDs with those for the reuse of surgical instruments.

## About the survey

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This survey focuses on **costs, timelines and procedures for the reprocessing of SUDs and the reuse of surgical instruments in the European Union** and was drafted based on desk research and previous interviews with key stakeholders.

This survey is structured into several parts:

- About you
- Reprocessing of SUDs
- Surgical instrument reuse practices

- Closing and thank you

The main part includes targeted questions that may vary depending on the stakeholder group you represent. This means that not all main parts may be visible for you.

The following stakeholder groups are kindly invited to take part in this survey:

- Manufacturers / Reprocessors
- Healthcare providers and institutions
- Laboratories
- Sterilization units

There are 18-30 questions depending on which stakeholder group you represent. Some questions are multiple choice, whilst others provide some free text and require you to fill in a table.

The survey should take approximately half an hour to complete. You may save answers and come back. Please make sure that you submit your response at the end by clicking on the 'submit' button.

## Data protection and consent to participate

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Acting in full compliance with EU competition law, and within its limits, the study team will keep any specific information (raw data) collected at the individual level strictly confidential and under no circumstances will individualised information be disclosed. The study team will ensure that the data is handled with the utmost care and protection. Only aggregated survey outcomes will be published and included in the final report.

I consent to participate in this survey in accordance with the Data Protection Notice and to the use of my answers in aggregated form for a report to DG SANTE/HaDEA which may be published.

[MedPro II Task 1.4 HADEA 2025 SC 0038 DPN survey final 25.11.2025.pdf](#)

## About you

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\* Please provide the name of your institution.

\* Please provide your email address.

\* Please provide your country.

Austria

- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- United States
- Japan
- Canada
- Other

\* See below for our definitions of the stakeholder groups:

**Manufacturer/Reprocessor** is an entity that takes a SUD—a device originally intended for one use on a single patient—and reprocesses (e.g., cleans, disinfects, sterilizes, tests, and repackages) it for reuse.

**Healthcare provider or institution** is the end user of SUDs or reused surgical instruments in patient care and who respectively must follow labelling and safety instructions or cleans, disinfects, and/or sterilizes surgical instruments according to validated procedures and manufacturer instructions to ensure patient safety. A healthcare institution can also be a reprocessor of SUDs in accordance with Art 17(3) MDR, where permitted. [Select this stakeholder group if you do not have an in house sterilisation unit or laboratory or if you](#)

are answering this survey from a more general healthcare institutional perspective.

**Laboratory** is responsible for scientific testing and validation related to cleaning, sterilization, and device performance.

- For reusable surgical instruments, they focus on process validation and contamination control.
- For SUD reprocessing, they could carry out the disinfection, cleaning, sterilization of a SUD as external reprocessors, ensuring the reprocessed device is safe and effective for reuse.

**Sterilisation unit** is located in hospital focusing on routine processing of reusable surgical instruments for safe reuse. In industrial or third-party reprocessing, it could carry out the disinfection, cleaning, sterilization of a SUD as external reprocessors, requiring validated sterilisation and full quality system compliance.

Please select the stakeholder groups you belong to (choose all that apply).

- Manufacturer/Reprocessor
- Healthcare provider/institution
- Laboratory
- Sterilisation unit
- Other

Which kind of healthcare provider/institution? (Please choose all that apply).

- Hospital
- Ambulatory surgery centre / day surgery clinic
- Outpatient medical centre
- Dental clinic / dental practice
- Other

Which kind of sterilisation unit?

- Hospital-based sterilisation unit
- External sterilisation service provider
- Other

Please specify

\* Does your company/institution reprocess single-use devices?

- Yes
- No

\* Does your company/institution process surgical instruments for reuse?

- Yes

No

## The reprocessing of single use devices

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### Staff

- \* How many people **in your institution** in total work on reprocessing SUDs? (Please indicate full time equivalents)

### Information about type and quantity of **single use devices**

- \* What is the **estimated annual number of SUDs** (i.e., volume/quantity) that your company/institution reprocesses?

Please fill in the following table about **types and volume of products** in your institution.

Type of SUD	<b>Rank</b> each type of SUD according to how frequently it is reprocessed in your institution, from <b>1 (most frequent) to 5 (least frequent)</b> . Leave blank if not applicable.	What is the estimated annual number of these specific categories of SUDs (i.e., volume/quantity) that your company/institution reprocesses?	Do you have any further comments?
Cardiovascular	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	<input type="text"/>	
General Surgery	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	<input type="text"/>	
Laparoscopic	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	<input type="text"/>	
Non-invasive	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	<input type="text"/>	
Other	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	<input type="text"/>	

If other, please specify here.

Comments

### Procedures, timelines, and costs of **reprocessing single use devices**

- \* What is the total **average length of time that the entire reprocessing cycle takes** across all products that you reprocess (excluding time for certification)?

Please provide the duration in numerical time, indicating the unit of time (e.g., 6 hours, 3 days, 1 week).

- \* What is the **average reprocessing cost** (including material, staff, etc.) per SUD in € Euros (EUR), excluding certification and validation?

Please fill in the following table with the appropriate option and to the best of your ability.

Steps in reprocessing cycle	Do you conduct the following?	How many people work on this? (in full time equivalents)	How long does this step usually take? (Please answer 'not applicable' if you do not conduct this step)	How much does this step usually cost on average per SUD in € Euros (EUR)? (Please answer 'not applicable' if you do not conduct this step)	Is this step outsourced? (Please answer 'not applicable' if you do not conduct this step)	Do you have any further comments?
Pre-use preparation (e.g., identifying origin, importing information for data transfer, applying serial number)	* <input type="radio"/> Yes <input type="radio"/> No		* <input type="radio"/> Not applicable <input type="radio"/> 0-<1 minutes <input type="radio"/> 1-<10 minutes <input type="radio"/> 10-<20 minutes <input type="radio"/> 20-<30 minutes <input type="radio"/> 30-<40 minutes <input type="radio"/> 40-<50 minutes <input type="radio"/> 50-<60 minutes <input type="radio"/> 1-<2 hours <input type="radio"/> 2-<4 hours <input type="radio"/> 4-<6 hours <input type="radio"/> 6-<8 hours <input type="radio"/> 8-<10 hours <input type="radio"/> 10-<12 hours <input type="radio"/> 12-<14 hours <input type="radio"/> 14-<16 hours <input type="radio"/> 16-<18 hours <input type="radio"/> 18-<20 hours <input type="radio"/> 20-<22 hours <input type="radio"/> 22-<24 hours <input type="radio"/> 1-<2 days <input type="radio"/> 2-<3 days <input type="radio"/> 3-<4 days <input type="radio"/> 4 or more days <input type="radio"/> 4 days	*	* <input type="radio"/> Not applicable <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Partly	

<p>Pre-use inspection (for defects, damage, sterility)</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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<p>Post-use cleaning (preparation for cleaning, pre-cleaning, cleaning, rinsing, disinfecting, drying)</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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<p>Testing for proof of function and to ensure that reprocessed product meets same standards as original product</p>	<p>*</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>		<p>*</p> <p><input type="radio"/> Not applicable</p> <p><input type="radio"/> 0-&lt;1 minutes</p> <p><input type="radio"/> 1-&lt;10 minutes</p> <p><input type="radio"/> 10-&lt;20 minutes</p> <p><input type="radio"/> 20-&lt;30 minutes</p> <p><input type="radio"/> 30-&lt;40 minutes</p> <p><input type="radio"/> 40-&lt;50 minutes</p> <p><input type="radio"/> 50-&lt;60 minutes</p> <p><input type="radio"/> 1-&lt;2 hours</p> <p><input type="radio"/> 2-&lt;4 hours</p> <p><input type="radio"/> 4-&lt;6 hours</p> <p><input type="radio"/> 6-&lt;8 hours</p> <p><input type="radio"/> 8-&lt;10 hours</p> <p><input type="radio"/> 10-&lt;12 hours</p> <p><input type="radio"/> 12-&lt;14 hours</p> <p><input type="radio"/> 14-&lt;16 hours</p> <p><input type="radio"/> 16-&lt;18 hours</p> <p><input type="radio"/> 18-&lt;20 hours</p> <p><input type="radio"/> 20-&lt;22 hours</p> <p><input type="radio"/> 22-&lt;24 hours</p> <p><input type="radio"/> 1-&lt;2 days</p> <p><input type="radio"/> 2-&lt;3 days</p> <p><input type="radio"/> 3-&lt;4 days</p> <p><input type="radio"/> 4 or more days</p> <p><input type="radio"/> 4 days</p>	<p>*</p>	<p>*</p> <p><input type="radio"/> Not applicable</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Partly</p>	
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<p>Post-use (re)assembling</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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<p>Post-use testing</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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<p>Post-use (re)packaging</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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<p>Sterilisation</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>
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<p>Post-use validation</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
<p>Transporting final product back to hospitals</p>						

If there are any further steps not mentioned above please identify them in this table and fill in to the best of your ability.

	Additional step	How many people work on this? (in full time equivalents)	How long does this step usually take?	How much does this step usually cost on average per SUD in € Euros (EUR)?	Is this step outsourced?	Do you have any further comments?
Additional step 1			<input type="radio"/> 0-<1 minutes <input type="radio"/> 1-<10 minutes <input type="radio"/> 10-<20 minutes <input type="radio"/> 20-<30 minutes <input type="radio"/> 30-<40 minutes <input type="radio"/> 40-<50 minutes <input type="radio"/> 50-<60 minutes <input type="radio"/> 1-<2 hours <input type="radio"/> 2-<4 hours <input type="radio"/> 4-<6 hours <input type="radio"/> 6-<8 hours <input type="radio"/> 8-<10 hours <input type="radio"/> 10-<12 hours <input type="radio"/> 12-<14 hours <input type="radio"/> 14-<16 hours <input type="radio"/> 16-<18 hours <input type="radio"/> 18-<20 hours <input type="radio"/> 20-<22 hours <input type="radio"/> 22-<24 hours <input type="radio"/> 1-<2 days <input type="radio"/> 2-<3 days <input type="radio"/> 3-<4 days <input type="radio"/> 4 or more days <input type="radio"/> 4 days	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Partly	

Additional step 2			<input type="radio"/> 0-<1 minutes <input type="radio"/> 1-<10 minutes <input type="radio"/> 10-<20 minutes <input type="radio"/> 20-<30 minutes <input type="radio"/> 30-<40 minutes <input type="radio"/> 40-<50 minutes <input type="radio"/> 50-<60 minutes <input type="radio"/> 1-<2 hours <input type="radio"/> 2-<4 hours <input type="radio"/> 4-<6 hours <input type="radio"/> 6-<8 hours <input type="radio"/> 8-<10 hours <input type="radio"/> 10-<12 hours <input type="radio"/> 12-<14 hours <input type="radio"/> 14-<16 hours <input type="radio"/> 16-<18 hours <input type="radio"/> 18-<20 hours <input type="radio"/> 20-<22 hours <input type="radio"/> 22-<24 hours <input type="radio"/> 1-<2 days <input type="radio"/> 2-<3 days <input type="radio"/> 3-<4 days <input type="radio"/> 4 or more days <input type="radio"/> 4 days	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Partly	

What are the **main exceptions** to this overall cycle?

For which SUDs do these exceptions apply and why?

Comments

## Procedures, timelines, and costs of certifying **single use devices and/or the reprocessing of single use devices**

\* Please choose the most appropriate choice below regarding certification.

- My company/institution has already received MDR certificates for the reprocessing of SUDs.
- My company/institution has already submitted an application for the MDR certification for the reprocessing of SUDs to a notified body.
- My company/institution has not started with the MDR certification for the reprocessing of SUDs.
- MDR certification for the reprocessing of SUDs is not applicable to my company/institution.
- I don't know.

Which MDR certificate? (Choose all that apply.)

- Certificates for reprocessing of SUDs in accordance with **Art. 17(2)** MDR
- Certificates in accordance with **Art. 17(5)** MDR (cf. Article 21(1) and Article 22 Commission Implementing Regulation (EU) 2020/1207)

## Regulatory and operational aspects of **single use devices**

\* What are the **main challenges** your institution has in complying with Article 17 MDR requirements?

\* What systems or tools does your institution use to **ensure traceability and documentation** of reprocessing steps (choose all that apply)?

*Between 1 and 4 selections*

- Barcode
- Laser etching
- IT system
- Other
- I don't know

\* If other please identify the tool/s.

\* Do you monitor **cost savings or environmental benefits** of reprocessing SUDs?

Yes

No

Comments

## The reuse cycle of surgical instruments

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### Staff

\* How many people **in your institution** in total work on processing surgical instruments for reuse? (Please indicate full time equivalents)

### Information about type and quantity of **reused surgical instruments**

\* What is the **estimated annual number of reusable surgical instruments** (i.e., volume/quantity) in your institution?

Please fill in the following table about **types and volume of reusable surgical instruments** in your institution.

Type of surgical instrument	Rank each type of surgical instrument according to how frequently it is reused in your institution, from <b>1 (most frequent) to 5 (least frequent)</b> . Leave blank if not applicable.	What is the estimated annual number of surgical instruments (i.e., volume/quantity) reused in your company/institution?	Do you have any further comments?
General surgery (scissors, forceps, clamps, etc.)	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		
Orthopaedic (e.g., chisels, reamers)	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		
Laparoscopic (trocars, scissors, etc.)	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		

ENT/Ophthalmic (e.g., specula)	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		
Dental/oral (forceps, elevators, etc.)	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		
Gynaecologic /urologic (e.g., dilators, specula)	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		
Endoscopic systems (rigid scopes, light cables, etc.)	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		

Other	* <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Not applicable		
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If other, please specify.

Comments

## Procedures, timelines, and costs of **surgical instrument reuse** practices

- \* What is the **total average length of time** that a reuse cycle takes (excluding transportation and storage, if applicable)?

Please provide a numerical answer with a unit of time (e.g., 6 hours, 3 days, 1 week).

- \* What is the total average length of time that **transportation and storage** take?

- \* What is the **total cost** (including personnel) in € Euros (EUR) of an average reuse cycle?

Please fill in the following table with the appropriate option and to the best of your ability.

We are aware that the data largely depend on the instrument. **If there are substantial discrepancies between the least and the most resource-intensive instruments, please indicate them in the free text field.**

Steps in reuse cycle	Do you conduct the following?	How many people work on this? (In full time equivalents)	How long does this step usually take? (Please answer 'not applicable' if you do <i>not</i> conduct this step)	What is the average total cost for this step per surgical instrument in € Euros (EUR)? (Please answer 'not applicable' if you do not conduct this step)  If data is <i>not</i> available per surgical instrument, please indicate costs per tray and state this in the comment column.	Is this step outsourced? (Please answer 'not applicable' if you do <i>not</i> conduct this step)	Do you have any further comments?
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<p>Transportation</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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Preparation	<p>*</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>		<p>*</p> <p><input type="radio"/> Not applicable</p> <p><input type="radio"/> 0-&lt;1 minutes</p> <p><input type="radio"/> 1-&lt;10 minutes</p> <p><input type="radio"/> 10-&lt;20 minutes</p> <p><input type="radio"/> 20-&lt;30 minutes</p> <p><input type="radio"/> 30-&lt;40 minutes</p> <p><input type="radio"/> 40-&lt;50 minutes</p> <p><input type="radio"/> 50-&lt;60 minutes</p> <p><input type="radio"/> 1-&lt;2 hours</p> <p><input type="radio"/> 2-&lt;4 hours</p> <p><input type="radio"/> 4-&lt;6 hours</p> <p><input type="radio"/> 6-&lt;8 hours</p> <p><input type="radio"/> 8-&lt;10 hours</p> <p><input type="radio"/> 10-&lt;12 hours</p> <p><input type="radio"/> 12-&lt;14 hours</p> <p><input type="radio"/> 14-&lt;16 hours</p> <p><input type="radio"/> 16-&lt;18 hours</p> <p><input type="radio"/> 18-&lt;20 hours</p> <p><input type="radio"/> 20-&lt;22 hours</p> <p><input type="radio"/> 22-&lt;24 hours</p> <p><input type="radio"/> 1-&lt;2 days</p> <p><input type="radio"/> 2-&lt;3 days</p> <p><input type="radio"/> 3-&lt;4 days</p> <p><input type="radio"/> 4 or more days</p> <p><input type="radio"/> 4 days</p>	<p>*</p>	<p>*</p> <p><input type="radio"/> Not applicable</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Partly</p>	
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<p>Inspection (for defects, damage, sterility)</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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<p>Cleaning (preparation for cleaning, pre-cleaning, cleaning, rinsing, disinfecting, drying)</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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Sterilisation	<p>*</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>		<p>*</p> <p><input type="radio"/> Not applicable</p> <p><input type="radio"/> 0-&lt;1 minutes</p> <p><input type="radio"/> 1-&lt;10 minutes</p> <p><input type="radio"/> 10-&lt;20 minutes</p> <p><input type="radio"/> 20-&lt;30 minutes</p> <p><input type="radio"/> 30-&lt;40 minutes</p> <p><input type="radio"/> 40-&lt;50 minutes</p> <p><input type="radio"/> 50-&lt;60 minutes</p> <p><input type="radio"/> 1-&lt;2 hours</p> <p><input type="radio"/> 2-&lt;4 hours</p> <p><input type="radio"/> 4-&lt;6 hours</p> <p><input type="radio"/> 6-&lt;8 hours</p> <p><input type="radio"/> 8-&lt;10 hours</p> <p><input type="radio"/> 10-&lt;12 hours</p> <p><input type="radio"/> 12-&lt;14 hours</p> <p><input type="radio"/> 14-&lt;16 hours</p> <p><input type="radio"/> 16-&lt;18 hours</p> <p><input type="radio"/> 18-&lt;20 hours</p> <p><input type="radio"/> 20-&lt;22 hours</p> <p><input type="radio"/> 22-&lt;24 hours</p> <p><input type="radio"/> 1-&lt;2 days</p> <p><input type="radio"/> 2-&lt;3 days</p> <p><input type="radio"/> 3-&lt;4 days</p> <p><input type="radio"/> 4 or more days</p> <p><input type="radio"/> 4 days</p>	<p>*</p>	<p>*</p> <p><input type="radio"/> Not applicable</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Partly</p>	
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<p>Transportation</p>	<p>*  <input type="radio"/> Yes  <input type="radio"/> No</p>		<p>*  <input type="radio"/> Not applicable  <input type="radio"/> 0-&lt;1 minutes  <input type="radio"/> 1-&lt;10 minutes  <input type="radio"/> 10-&lt;20 minutes  <input type="radio"/> 20-&lt;30 minutes  <input type="radio"/> 30-&lt;40 minutes  <input type="radio"/> 40-&lt;50 minutes  <input type="radio"/> 50-&lt;60 minutes  <input type="radio"/> 1-&lt;2 hours  <input type="radio"/> 2-&lt;4 hours  <input type="radio"/> 4-&lt;6 hours  <input type="radio"/> 6-&lt;8 hours  <input type="radio"/> 8-&lt;10 hours  <input type="radio"/> 10-&lt;12 hours  <input type="radio"/> 12-&lt;14 hours  <input type="radio"/> 14-&lt;16 hours  <input type="radio"/> 16-&lt;18 hours  <input type="radio"/> 18-&lt;20 hours  <input type="radio"/> 20-&lt;22 hours  <input type="radio"/> 22-&lt;24 hours  <input type="radio"/> 1-&lt;2 days  <input type="radio"/> 2-&lt;3 days  <input type="radio"/> 3-&lt;4 days  <input type="radio"/> 4 or more days  <input type="radio"/> 4 days</p>	<p>*</p>	<p>*  <input type="radio"/> Not applicable  <input type="radio"/> Yes  <input type="radio"/> No  <input type="radio"/> Partly</p>	
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If there are any further steps not mentioned above please identify them in this table and fill in to the best of your ability.

	Additional step	How many people work on this? (in full time equivalents)	How long does this step usually take?	How much does this step usually cost on average per SUD in € Euros (EUR)?	Is this step outsourced?	Do you have any further comments?
Additional step 1			<input type="radio"/> 0-<1 minutes <input type="radio"/> 1-<10 minutes <input type="radio"/> 10-<20 minutes <input type="radio"/> 20-<30 minutes <input type="radio"/> 30-<40 minutes <input type="radio"/> 40-<50 minutes <input type="radio"/> 50-<60 minutes <input type="radio"/> 1-<2 hours <input type="radio"/> 2-<4 hours <input type="radio"/> 4-<6 hours <input type="radio"/> 6-<8 hours <input type="radio"/> 8-<10 hours <input type="radio"/> 10-<12 hours <input type="radio"/> 12-<14 hours <input type="radio"/> 14-<16 hours <input type="radio"/> 16-<18 hours <input type="radio"/> 18-<20 hours <input type="radio"/> 20-<22 hours <input type="radio"/> 22-<24 hours <input type="radio"/> 1-<2 days <input type="radio"/> 2-<3 days <input type="radio"/> 3-<4 days <input type="radio"/> 4 or more days <input type="radio"/> 4 days	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Partly	

Additional step 2			<input type="radio"/> 0-<1 minutes <input type="radio"/> 1-<10 minutes <input type="radio"/> 10-<20 minutes <input type="radio"/> 20-<30 minutes <input type="radio"/> 30-<40 minutes <input type="radio"/> 40-<50 minutes <input type="radio"/> 50-<60 minutes <input type="radio"/> 1-<2 hours <input type="radio"/> 2-<4 hours <input type="radio"/> 4-<6 hours <input type="radio"/> 6-<8 hours <input type="radio"/> 8-<10 hours <input type="radio"/> 10-<12 hours <input type="radio"/> 12-<14 hours <input type="radio"/> 14-<16 hours <input type="radio"/> 16-<18 hours <input type="radio"/> 18-<20 hours <input type="radio"/> 20-<22 hours <input type="radio"/> 22-<24 hours <input type="radio"/> 1-<2 days <input type="radio"/> 2-<3 days <input type="radio"/> 3-<4 days <input type="radio"/> 4 or more days <input type="radio"/> 4 days	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Partly	
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What are the main **exceptions** to this overall cycle?

For which surgical instruments do these exceptions apply and why?

Comments

## Procedures, timelines, and costs for the validation of the process to **reuse surgical instruments**

My company/institution already has a **validated process in place for processing surgical instruments for reuse**.

Note: For reusable surgical instruments, the involvement of a notified body is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

- Yes
- No

Please elaborate on the validation process by filling in the table below to the best of your ability.

Validation type	Is this validation step applicable to your company /institution?	How long does this process take for reused surgical instruments (e.g., 35 minutes, 6 hours, or 'not applicable')?	What is the total average cost for this certification in € Euros (EUR)? (Can be 'not applicable')
Cleaning	* <input type="radio"/> Yes <input type="radio"/> No	*	* <input type="text"/>
Disinfecting	* <input type="radio"/> Yes <input type="radio"/> No	*	* <input type="text"/>
Packaging /sterilising	* <input type="radio"/> Yes <input type="radio"/> No	*	* <input type="text"/>
Maintenance	* <input type="radio"/> Yes <input type="radio"/> No	*	* <input type="text"/>
Functional testing	* <input type="radio"/> Yes <input type="radio"/> No	*	* <input type="text"/>

Comments

## Regulatory and operational aspects of **reusing surgical instruments**

\* Which specific **national or EU standards (e.g., EN ISO) or guidelines** does your institution follow for the reuse of surgical instruments?

\* What are the **main challenges** your institution has in reusing surgical instruments?

\* What systems or tools does your institution use to **ensure traceability and documentation** of reuse cycles (choose all that apply)?

- Barcode
- Laser etching
- IT system
- Other
- I don't know

\* Do you monitor **cost savings or environmental benefits** of reusing surgical instruments?

- Yes
- No

\* How do you monitor cost savings or environmental benefits?

Comments

## Further contribution/information

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\* Can you suggest any additional contacts who may be relevant to consult or involve in this study?

\* Do you know of any further literature, databases, or methodological documents that could support this research?

\* Would you be interested and available to continue contributing to this project, for example by participating in a further interview?

Yes

No

Is there anything else you would like to add?

## Contact

[Contact Form](#)