

I Background

With the introduction of Regulation EU 2017/745 (MDR¹), the conformity assessment procedure for "reusable surgical instruments" was redefined.

In principle, reusable surgical instruments must be classified according to the second indent of Rule 6:

All surgically invasive devices intended for transient use are classified as class IIa unless they[...] are reusable surgical instruments, in which case they are classified as class I.

Typically, these devices are referred to as class I reusable medical devices (class I, reusable or class Ir). For these products, the legislator has laid down stricter requirements for the conformity assessment procedure.

MDR, Annex VIII, point 2.3:

„Reusable surgical instrument“ means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

The manufacturer shall apply a procedure either according to MDR Annex IX Chapter I (quality management system) or according to MDR Annex XI Part A (production quality assurance) with a notified body. For these products, however, the involvement of the notified body in those procedures shall be 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".

II Requirements for technical documentation

The requirements for technical documentation are determined in general terms in Annexes II and III of the MDR. These also apply to class I medical devices and their subclasses (e.g. class Ir).

An overview of the requirements for technical documentation has been published by mdc on its website in the download area.

The complete technical documentation is submitted to the notified body, a detailed examination of the contents of a Class Ir medical device, however, is only carried out for the above-mentioned aspects related to reprocessing.

III (Special) contents of the technical documentation

This document shall consider special requirements for class Ir devices

1 Device description and specification

1.1 General description of the device including product variants and intended purpose

For general requirements see MDR Annexes II and III, special aspects for Ir devices:


- Description of the different variants (sizes, purpose, surface treatments & coating, etc.)
- Summary information from the instructions for use on mechanical and manual reprocessing, including the most important parameters.
- Summary of the accessories required for reprocessing.
- Description of the surgical techniques the devices are used for - in particular in consideration of the expected or possible contamination (e.g. blood, nerves, bone, lymph, urine, stool, tissue adhesive, bone cements, etc.).

1.2 Unique Device Identification („UDI system“)

For general requirements see MDR Annexes II and III.

Direct labelling of reusable products with extended transition period of 2 years according to general labelling obligation.

¹ Regulation (EU) 2017/745 on medical devices - <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&qid=1559821569806&from=EN>

	Technical documentation for reusable surgical instruments (class Ir)	001/07.2019
		ID: 3680

1.3 Classification

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

1.4 Declaration of Conformity (DoC)

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

1.5 Description of the principles of operation

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

Description of the principles of operation of the devices including accessories required for application and reprocessing.

1.6 Summary of safety and clinical performance (only for implantable and class III medical devices)

Not applicable for medical devices of class Ir.

1.7 Raw materials, components, packaging materials

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

Consideration of the compatibility of the raw materials with the reprocessing processes (cleaning / disinfection / sterilization) - especially for medical devices containing (parts of) plastic.

1.8 Tissues of human or animal origin

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

1.9 Previous generations

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

2 Labelling and instructions for use / reprocessing instructions

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

- Requirements for information on the reprocessing of medical devices have to be taken into account. The state of art is EN ISO 17664.
- Requirements for reprocessing - e.g. sterilization - must take into account the recognized state of the art in the intended European member states (e.g. KRINKO-BfArM recommendation in Germany: Sterilization with saturated steam at 134 °C, for 5 minutes). Deviations must be justified appropriately (risk management) and marked (e.g. in the instructions for use).

3 Description of the design and manufacturing

3.1 Description of the design

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

3.2 Description of the manufacturing

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

Evaluation of those production steps whose results can have an effect on the reprocessing or whose success can be endangered by a (multiple) reprocessing. In particular, compatibility with the specified reprocessing procedures must be evaluated:

- Marking (by etching, laser, milling, etc.)
- Surface treatment (coating, anodizing, passivating, powder coating, coating, etc.)
- Joint connections (bonding, welding, soft- and hard soldering)

3.3 Description of quality control

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

3.4 Outsourced processes, subcontractors

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

4 General Safety and Performance Requirements

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

5 Benefit-risk analysis and risk management

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

- Special requirements due to the nature of the product (e.g. Critical B according to KRINKO-BfArM recommendation)
- Influence of multiple reprocessing
- How can the end of life be recognized / must the reprocessing frequency be limited?
- Consideration of influences of geometry and materials (special difficulties for reprocessing, special requirements, where necessary, guidance may be given in the instructions for use as a risk control measure!)
- Consideration of influences of the application
- Consideration of reprocessing of the product (media, foreseeable misuse, etc.)

6 Product verification and validation

6.1 Biocompatibility

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

Evaluation of the influence of (repeated) reprocessing on the selected materials and surfaces.

6.2 Physical, chemical and microbiological testing

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.3 Electrical safety and electromagnetic compatibility EMC

Not applicable for class Ir medical devices.

6.4 Software verification and validation

Not applicable for class Ir medical devices.

6.5 Stability, including shelf life

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

Within the validation of the reprocessing, the manufacturer must state clearly, by what means it can be seen that the product cannot be reused (e.g. specify the maximum number of reprocessing or application of the product and provide appropriate evidence of this number or evidence of material wear or loss of product integrity). If appropriate - taking into account the results of risk management - the entire application and reprocessing process must be run through as part of the validation. The aspects of how the functionality can be tested must also be taken into account.

6.6 Other pre-clinical tests

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.7 Clinical evaluation

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.8 PMCF (post-market clinical follow-up) plan and PMCF evaluation report

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.9 Medicinal products as defined in Directive 2001/83/EC

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.10 Tissues or cells of human or animal origin

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.11 Substances that are intended to be introduced into the human body

Not applicable for class Ir medical devices.

6.12 CMR or endocrine-disrupting activity

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.13 Sterility and controlled environmental conditions

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.14 Measuring function

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

For Class I products that are both reusable surgical instruments and have a measurement function, the effects of reprocessing on the measurement function must be evaluated and documented.

6.15 Combination with other devices

For general requirements see MDR Annexes II and III, no additional special requirements for class Ir products.

6.16 Hygienic (re)processing of devices

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

As part of the technical documentation the manufacturer shall provide a justification, description and validation for the (re)processing of medical devices which either have to be reprocessed before first use or are intended for multiple (surgical/invasive) use.

The documentation must prove the suitability of the reprocessing specifications described in the instructions for use – in consideration of the current state of the art. The verifications shall be prepared taking into account the requirements of EN ISO 17664.

The documentation typically consists of:

- Planning of the activity (validation) including definition of acceptance criteria
- Evidence of execution (e.g. test reports from qualified, preferably accredited, external laboratories, etc.)
- Evaluation of the activity: Were the acceptance criteria fulfilled?

Process steps to be taken into account within the reprocessing process:

- Pre-cleaning
- Cleaning (mechanical and manual)
- Disinfection (mechanical and manual)
- Functional testing and maintenance
- packaging
- sterilization
- (storage)

If the validation is based on a worst-case product, the assignment of the individual product or variant must be considered and justified. Essential aspects for comparability with a worst-case product:

- Geometric aspects (lumina, blind holes, undercuts, gaps, flushing connections)
- Materials (stainless steels, plastics, etc.)
- Functional properties (movable-rigid, dismountable, flushable, non-flushable, etc.)
- Surface properties (roughness, coatings, passivation, lettering, etc.)
- Expected contamination (blood, tissue, bone, urine, stool, tissue adhesive, bone cement, ...?)
- if applicable: the type of sterilization and packaging

Structure of the evaluation results:


Typical contents of the validation plan - Plan of the worst-case validation:

- Regulation of the organisation, responsibilities and competences for the execution of the validation and the associated risk assessment
- Definition of the responsible person/team for the evaluation of the result protocols
- List of the contamination/degree of contamination to be expected on the product
- Justification and comparison with worst-case products
 - o consideration of the above-mentioned aspects
 - o Identification of the areas most difficult to clean
 - o Identification of critical influences
- The validation plan contains all stages of the reprocessing including the respective process descriptions:
 - o Cleaning
 - o Disinfection
 - o Drying
 - o Function test and maintenance
 - o Packaging
 - o Sterilization
 - o Function test
- Definition of acceptance conditions or acceptance criteria and basic methodological specifications

Typical contents of the validation report:

1. Evaluation of the basic performance of the cleaning process
Installation Qualification / IQ and Operational Qualification / OQ) for the respective process section
e.g. independent test reports on the performance of the cleaning and disinfection device (e.g. EN ISO 15883-x) or the sterilizer (e.g. EN 13060, EN 285, etc.).

2. Process performance qualification (PPQ) for the respective process section applied to the concrete (worst-case) product:
- Cleaning, including pre-cleaning
 - Machine cleaning and manual cleaning
 - o Description and justification of test soils and detection methods
 - o Definition of acceptance criteria (e.g. residual protein, optical cleanliness, wipe test, particle tests, radioactive markers, etc.)
 - o Justification for the chosen test method (e.g. determination of recovery rate)
 - o Justification for the selection of the cleaning medium (alkaline, enzymatic, neutral)
 - o Evaluation of the cleaning performance (were the acceptance criteria met) - (e.g. external test report)
 - o Evaluations/considerations for the removal of the cleaning medium - (e.g. external test report)
 - o Assessment of the compatibility of the cleaning process with the medical device
 - o Evaluation of long-term consequences (number of reprocessings under consideration of life expectancy)
 - o Assessment of the applicability of the worst-case validation for all products and variants considered within the technical documentation
 - Disinfection
 - o Confirmation of the suitability of the worst-case product
 - o Description and justification of the disinfection process: (chemical, thermal, chemo-thermal)
 - o Testing with at least one test organism that can be regarded as particularly resistant
 - o Evaluation of the depletion of the test organism (e.g. external test report)
 - o Assessment of the compatibility of the disinfection process with the tested medical device
 - o Evaluation of long-term consequences (number of reprocessings under consideration of life expectancy)
 - o Assessment of the applicability of worst-case validation for all products and variants considered within the scope of the technical documentation
 - Packaging
 - o Confirmation of the suitability of the worst-case product
 - o Description and justification of the packaging process
 - o Assessment of the compatibility of the packaging material with the tested medical device and the selected sterilization method
 - o Assessment of the applicability of worst-case validation for all products and variants considered within the scope of the technical documentation
 - Sterilization:
 - o Confirmation of the suitability of the worst-case product
 - o Description and justification of the sterilization process: (saturated steam, dry heat, ethylene oxide, formaldehyde, plasma sterilization, ionising radiation, etc.)
 - o Test with at least one test organism considered to be particularly resistant.
 - o Evaluation of the depletion of the test organism (e.g. external test report)
 - o Assessment of the compatibility of the disinfection process with the tested medical device
 - o Evaluation of long-term consequences (number of reprocessings under consideration of life expectancy)
 - o Assessment of the applicability of the worst-case validation for all products and variants considered within the scope of the technical documentation
 - Summary report on the results
 - o Assessment of whether the individual acceptance criteria have been met
 - o Evaluation of the suitability of the individual process steps for the reprocessing process and, based on this, evaluation of the efficiency of the entire reprocessing process.
 - o Evaluation of the suitability of the procedures described in the instructions for use, taking into account the results of the validation.
 - o Consideration of special risks (e.g. restrictions, deviations from the "recognised state of the art", special features) in the risk management and the instructions for use

	Technical documentation for reusable surgical instruments (class Ir)	001/07.2019
		ID: 3680

6.17 Evaluation of expert reports/opinions from consultation procedures

Not applicable to class Ir medical devices.

7 Data from post-market surveillance

For general requirements see MDR Annexes II and III, in addition, special aspects for class Ir devices:

Special consideration within the framework of the PMS process of how feedback from reprocessing or problems with reprocessing is collected and systematically evaluated. These should in particular take into account aspects of multiple reprocessing. Both reactive and proactive market surveillance must be included.