This form serves to record the scope of certification of medical devices of the so-called class Ir and the calculation basis to be derived from it for the preparation of quotations and is considered a supplementary document to the **Questionnaire for a quotation – Medical devices** which you can also find on our website [www.mdc-ce.de/en](http://www.mdc-ce.de/en) in the download area.

Devices which meet the following criteria are classified as medical devices of class Ir:

* Classification applied in accordance with Rule 6, 2nd indent: 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.
* ‘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 sterilization have been carried out.’

The manufacturer must follow a procedure either according to Regulation (EU) 2017/745 Annex IX Chapter I (Quality Management System) or according to Annex XI Part A (Production Quality Assurance) with a Notified Body. For these devices, however, the involvement of the Notified Body in these procedures 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.’

**Information on the company**

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| --- | --- |
|  | Main address (certificate address) |
| Name and legal form of the company: |  |
| Date of the questionnaire: |  |
| Date of the list of medical devices: |  |

**Information on the reprocessing instructions**

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| 1. Summary information on the reprocessing procedure to be applied as described in the reprocessing instruction: | Please give a short summary of the procedures (including parameters) which are listed in the reprocessing instructions. |
| 1. Criteria for limitations and restrictions on reprocessing: | Please state your criteria/information for limitations/restrictions concerning reprocessing as described in the reprocessing instructions. |

**Scope**

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| --- | --- |
| 1. Number of devices included in the scope of certification applied for: |  |
| 1. Application for the following devices/device groups: | Please indicate how and according to which criteria you have formed the device groups/device families in order to prove the reprocessing capability. |
| 1. Number of device groups: |  |
| 1. Number of Technical Documentation of your class Ir devices: |  |
| 1. Total number of the underlying reprocessing validations: | Please enter here the number of reprocessing validations that form the basis for these devices/device families in class Ir. |
| 1. In case of outsourced verification of the reprocessing capability:  (e.g. to a supplier who is in possession of an own and complete documented reprocessing validation) | Not applicable  Applicable  If the verification of the reprocessing capability of your devices has been outsourced, for example to a supplier who is in possession of his own and complete reprocessing validation documentation, please describe here how you evaluate this data, which criteria you have defined and whether there are any further regulations so that you meet the requirements as a legal manufacturer. |

**Selection of the representative medical device to be tested with regard to reprocessing capability**

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| 1. Worst case description: | Please briefly summarise how you have defined the worst case scenario for the reprocessing validation. Which criteria/influencing factors were relevant? Which system was used? | |
| 1. Total number of worst case devices: | If you have one or several worst case devices as a basis to evaluate all sub-processes of the reprocessing, please indicate the respective number here. | |
| 1. Indication of separately considered worst-case devices with regard to the sub-processes of reprocessing: | Not applicable  Applicable  If you have one or several worst case devices as a basis for evaluating the sub-processes cleaning, disinfection, sterilisation and/or service life separately, please indicate the respective number with a brief description. | |
| 1. Indication of the materials of the devices, which were taken into account for reprocessing validation: | Please list here all materials of the devices you have taken into account for reprocessing validation. | |
| 1. Do the devices have special surface properties that may affect reprocessing? | Not applicable  Applicable  Please indicate any surface treatments and/or coatings applied to your devices. If applicable, please list other surface characteristics that have been identified as influencing factors for treatment. | |
| 1. Supplementary special reprocessing instructions  (e.g. supplementary assembly-disassembly instructions, other necessary aids such as greases/oils, special accessories): | Not applicable  Applicable  Please provide additional information for your devices which is important for the reprocessing capability. For example, supplementary assembly-disassembly instructions or other aids such as fats/oils which are necessary for the functionality. Are there any special accessories which must be used to ensure the reprocessability? | |
|  | |  |  |
| Place, date | |  | Name and signature or  name only in case of electronic transmission |