Guide for medical device manufacturers

CZECH METROLOGY INSTITUTE

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LIST OF ABBREVIATIONS

CMI	Czech Metrology Institute
EU	European Union
EUDAMED	European Database on Medical Devices
GSPR	General Safety and Performance Requirements
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation of the European Parliament and Council (EU) 2017/745
PMCF	Post Market Clinical Follow up
PMS	Post-Market Surveillance
PSUR	Periodic Safety Update Reports
SRN	Single Registration Number
SÚKL	State Institute for Drug Control
SW	Software
TD	Technical Documentation
UDI	Unique Device Identification
ÚNMZ	The Czech Office for Standards, Metrology and Testing
WET	Well-Established Technology
MD	Medical Device

1. ABOUT CMI

The Czech Metrology Institute (CMI) is a new Notified Body under the MDR

On December 22, 2023, the Czech Metrology Institute (CMI) was officially designated as a Notified Body following Regulation 2017/745.

Confirmation of authorisation to carry out the activities of a notified body in the field of medical devices conformity assessment according to the MDR along with the scope and limitation for this activity (list of MDR codes) can be found in the database of the European Commission Single Market Compliance Space or in the official confirmation document issued by the Czech Office for Standards, Metrology and Testing (ÚNMZ).

CMI also performs post-certification (surveillance) activities, which are necessary to maintain the validity of the medical device certification according to the MDR.

CMI's services are provided by a broad team of highly skilled professionals with extensive experience covering all relevant fields. CMI's aim and vision is to provide a high level of quality service with an emphasis on impartiality and objective evaluation of all information obtained.

More information about us on our website https://www.cmi.cz/mdr.

CMI's Scope for Conformity Assessment

CMI is an authorized notified body according to the MDR for the conformity assessment of the following classes of medical devices:

- Is – medical devices placed on the market in a sterile state
- Im – medical devices with a measuring function
- Ir – reusable surgical instruments
- IIa
- IIb

And the following conformity assessment procedures:

- Annex IX Chapter I and III MDR – assessment based on a quality management system
- Annex IX Chapter II MDR – assessment of the technical documentation
- Annex XI, part A MDR – assessment based on product conformity verification

CMI has a range of 20 basic MDR codes that reflect design and intended purpose (MDA/MDN) available, and 18 horizontal MDR codes (MDS and MDT). Specific codes and their limitations are available on our website in the Conformity Assessment Scope section.

Contacts and more information

For further clarification and other questions, please visit our website: https://www.cmi.cz/mdr

Notified bodies under valid legislation are not allowed to provide consulting services to those interested in the conformity assessment. Questions of this kind therefore cannot be answered.

2. REQUIREMENTS FOR MANUFACTURERS

Manufacturers are obliged to undergo the conformity assessment process under the MDR and issue a declaration of conformity, before placing their device on the market. Manufacturers bear the primary responsibility for their device that has to meet all the requirements according to the MDR and other relevant legal and technical regulations, before being placed on the EU market.

For the conformity assessment of the medical device classes Is, Im, Ir, IIa, IIb and III it is also necessary to involve a third party that is a notified body. Their role is to verify and declare, that the manufacturer‘s quality management system, technical documentation, parameters and production processes are aligned with the MDR and other relevant legal and technical regulations.

Notified bodies issue the relevant certificate after successfully completing the assessment process. Following this, the manufacturer can issue a declaration of conformity of the medical device and affix the CE marking to it as a declaration of compliance with all the requirements set out in the MDR and the relevant harmonised regulations.

2.1 New MDR Requirements

Changes to the MDR are often seen as revisions of the original requirements, but this isn't accurate. Although the conformity assessment methodology is based on the same foundations as it was for the MDD, and many of its requirements generally remain part of the new legislation, the MDR is, in fact, a new regulation with many new requirements and a new required structure, and must be approached as such.

In comparison to the MDD, the MDR puts greater emphasis on the medical devices' safety throughout its whole lifecycle, which must be supported by robust clinical data. Furthermore, it provides greater transparency by publicising more information on certified medical devices, conducted studies and clinical trials or post-market surveillance, which is all provided in the European Database on Medical Devices (EUDAMED) platform.

New Requirements of MDR for Medical Device Manufacturers

- Manufacturers must prove conformity with the General Requirements for Safety and Efficiency (Annex I of the MDR).
- Manufacturers must have a person responsible for regulatory compliance (Article 15 of the MDR). Manufacturers are required to designate this person within their organisation, and the person so designated must meet specified qualification criteria, and is ultimately responsible for compliance with the requirements of the MDR. The requirements in this regard are more lenient for micro and small enterprises, which can outsource this person.
- Manufacturers are obliged to register themselves and their devices in the European Database on Medical Devices (EUDAMED).

New Requirements of MDR for Medical Devices

- Strengthening of certain classification rules (Annex VIII of the MDR). A medical device must be assigned to one of the risk classes according to the level of risk, duration and degree of invasiveness. Some medical devices are now assigned to a higher risk class and thus require a more demanding conformity assessment process.
- The technical files have been given a new more detailed structure and content (Annex II and III of the MDR).
- The launch of a Unique Device Identification (UDI) system that allows manufacturers and institutions to trace a specific medical device through the supply chain. The manufacturer must provide a UDI system for each of its medical devices (Article 27 MDR, Annex VI MDR).
- Strengthening of requirements in the areas of clinical evaluation, post-market clinical follow-up (PMCF) and clinical trials (Article 61 MDR, Annex XIV MDR).
- Requirement of more comprehensive clinical evidence, in particular for Class III medical devices and implantable medical devices, in relation to stricter conditions for the demonstration of equivalence (Article 61 MDR). In case manufacturers do not have sufficient clinical evidence to demonstrate the safety and efficacy of a medical device, they are generally required to conduct a full clinical evaluation (Annex XV MDR).
- Introduction of stricter and more comprehensive post-market surveillance (PMS) of medical devices to minimize the risks associated with unsafe devices (Article 83 MDR). Obligation to collect and maintain post-market clinical data as part of an ongoing assessment of potential risks. In many cases, a regularly updated PSUR is also required (Article 86 MDR).
- Obligation to periodically produce a Summary of Safety and Clinical Performance Data for implantable medical devices and Class III medical devices (Article 32 of the MDR).

New MDR Requirements for Certification of Medical Devices

- Extension of the scope of the Regulation (Article 1 of the MDR), which now covers a wider range of products than previously under the MDD. A specific example of newly covered medical devices is the group of products without a specified medical purpose (Annex XVI of the MDR) or devices designed to prevent or predict a disease or health condition.

- Increased involvement of notified bodies in the conformity assessment of medical devices of risk class I, specifically for devices placed on the market in a sterile state (Is), devices with a measuring function (Im) or reusable surgical instruments (Ir). In these cases, the notified body always assesses the context of the device as it relates to these named aspects (Article 52, point 7 of the MDR).
- The notified body conformity assessment process is more comprehensive and detailed than previously (Annex VII, point 4.5 of the MDR, Annexes IX to XI of the MDR).

2.2 Step by step MDR requirements implementation into your system

Are you planning to implement MDR requirements in your quality management system? Below you will find the most important steps to help you prepare for what awaits you.

1. Baseline Evaluation

- Educate your management on the importance of the MDR and the related consequences for your company.
- Make a realistic assessment of the current state of the company: employees and their qualifications, financial resources, state of internal regulations, current quality of documentation, etc.

2. Initial analysis

- Assess the impact of implementing MDR on your company, products, internal processes and budget.
- Check the new definition of a medical device to see if your product falls under it.
- Review the new classification rules in Annex VIII of the MDR and classify your medical device.
- Learn the conformity assessment procedures and identify the one suitable for your medical device.
- Identify necessary changes to your existing technical documentation.
- Examine the adequacy of risk management and identify gaps.
- Ensure proper product labeling and implement UDI.
- Identify the necessary adjustments to your quality management system to meet the new MDR requirements.
- Contact a selected notified body, send them a non-binding inquiry and find out whether they have the capacity to assess your device.

3. Clinical Area

- Check the adequacy of the clinical evidence and, if necessary, consider addition to the required extent (clinical trial, etc.).
- Ensure compliance with device traceability obligations and prepare for new vigilance requirements.
- Prepare a procedure for post-market clinical follow-up.

4. Legal Aspects

- Identify the person responsible for regulatory compliance and ensure that this person is properly qualified and trained.
- Register your company as a manufacturer and obtain the Single Registration Number (SRN).
- Ensure that your product liability insurance is sufficient.

5. Product Portfolio

- Analyse your product portfolio. Keep in mind the costs of possible changes in medical device classification and new conformity assessment processes, as well as the costs of the elimination of insufficiency of technical documentation, etc.
- Verify the readiness of your suppliers and distributors and their ability to fulfil the specified requirements.

6. Implementation Plan

- Create a detailed implementation plan defining the sub-steps you will need to take to implement all MDR requirements.
- Pay particular attention to the transition period, the associated requirements for its use as well as the availability of your notified body.

7. Implementation of Requirements

- Execute the individual sub-steps according to the implementation plan.
- Ensure that a project team is available to carry out all parts of the implementation and that responsibilities for sub-steps are clearly defined.
- Establish regular review days to assess progress against the implementation plan and identify potential risks.

8. Certification

- Apply for medical device conformity assessment and sign a contract with a notified body.
- Start the conformity assessment process with the notified body in order to obtain the certificate.
- Obtain the certificate, draw up a declaration of conformity and place your medical device on the market.

3. MEDICAL DEVICE CLASSIFICATION

Before the notified body starts the conformity assessment process, the manufacturer shall perform and document the qualification and classification of their product according to the MDR. Firstly, the manufacturer has to provide a justification as to whether their product falls under the definition of a medical device according to Article 2 of the MDR (qualification). Subsequently, they shall detirmine its risk class in accordance with Annex VIII of the MDR (classification).

When classifying medical devices, it is important to be familiar with the terms and implementation rules defined in the MDR, which are key to determining the correct risk class of a device. Most of the terms are explained in the following chapter.

3.1 Helpful Terms

Annex VIII of the MDR separetes the classification rules into the areas of non-invasive devices (rules 1-4), invasive devices (rules 5-8), active devices (rules 9-13) and special rules (rules 14-22).

Invasive and active devices are defined in Article 2 of the MDR. Other useful definitions can also be found there. Definitions supplementing the classification rules are included in Annex VIII of the MDR.

Duration of Use

The MDR separets medical devices in terms of duration of use into three categories:

- Transient MD – normally intended for continuous use for less than 60 minutes;
- Short term MD – normally intended for continuous use for between 60 minutes and 30 days;
- Long term – normally intended for continuous use for more than 30 days.

In addition, the implementation rules set out in Annex VIII of the MDR define the term 'continuous use' as:

a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and

b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

Invasive Device

An invasive device is one, which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation.

Active Device

Any device the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

Body Orifice

Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically Invasive Device

a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and

b) a device which produces penetration other than through a body orifice.

Reusable Surgical Instrument

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.

Active Therapeutic Device

any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

Active Device Intended for Diagnosis and Monitoring

any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

Central Circulatory System

The following blood vessels: *arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens do bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior a vena cava inferior.*

Central Nervous System

The brain, meninges and spinal cord.

Injured Skin or Mucous Membrane

An area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

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;

Nanomaterial

Natural material, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm.

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials.

Particle

For the purposes of the definition of nanomaterial, means a minute piece of matter with defined physical boundaries.

Agglomerate

For the purposes of the definition of nanomaterial, means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.

Aggregate

for the purposes of the definition of nanomaterial, means a particle comprising of strongly bound or fused particles.

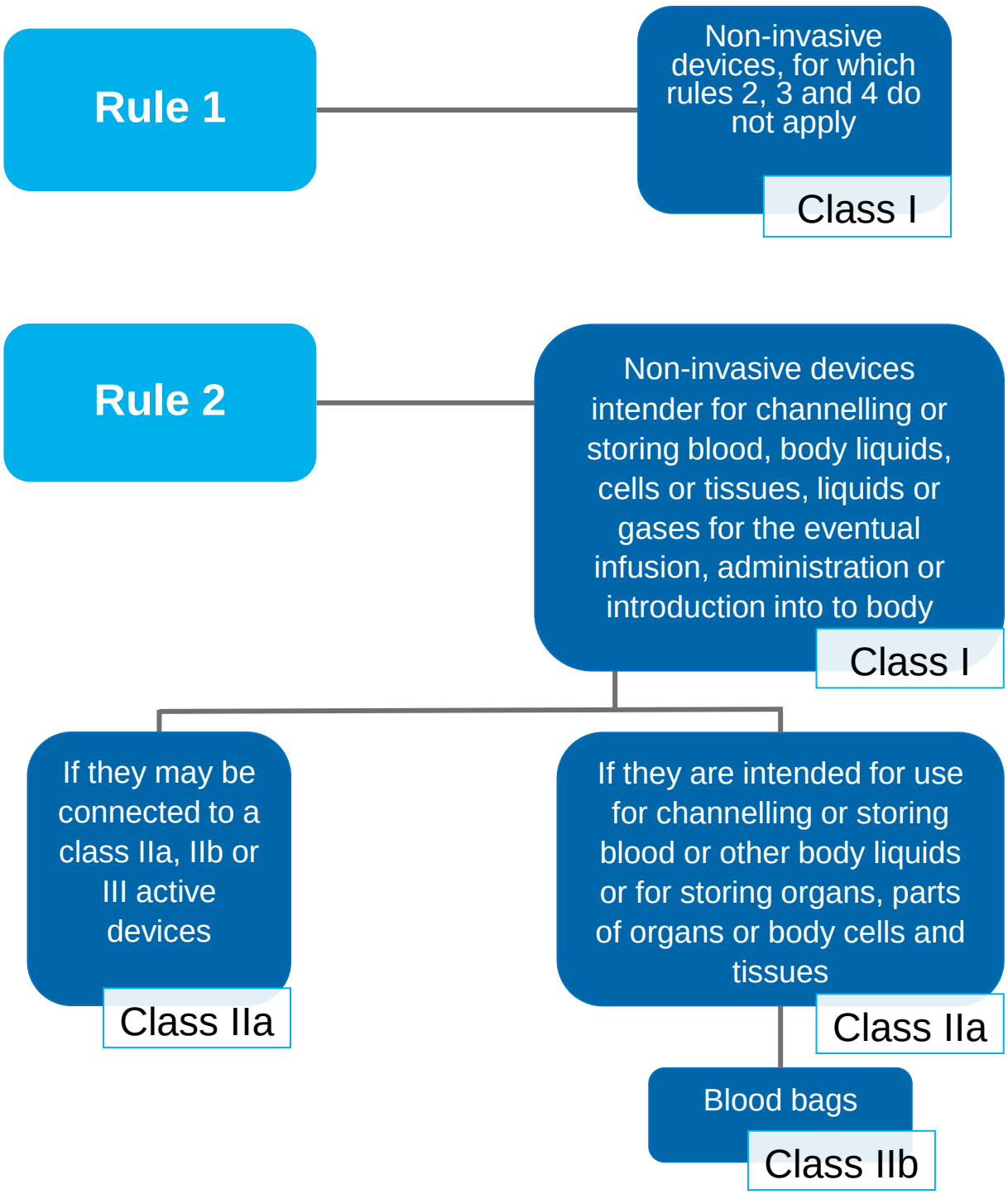
Implementing Rules

When determining the risk class of medical devices, it is important to keep in mind the rules set out in Chapter II of Annex VIII of the MDR:

- Application of the classification rules shall be governed by the intended purpose of the devices.
- If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device shall be classified in their own right separately from the device with which they are used.
- Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.
- If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.
- If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.
- A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

3.2 Medical Devices Classification Rules

NON-INVASIVE DEVICES



Rule 3

Non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other liquids or other liquids intended for implantation or administration into the body

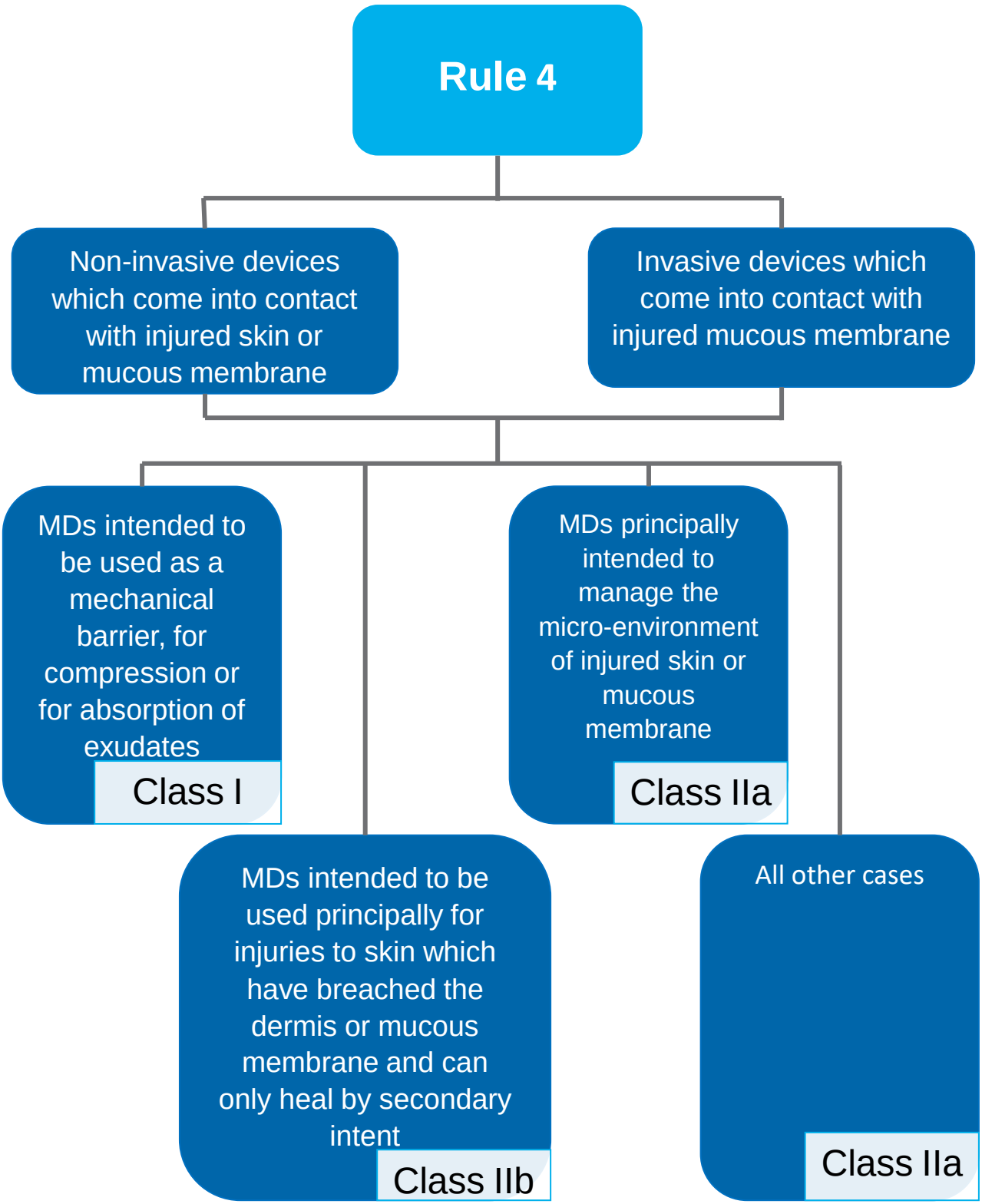
Class IIb

If the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat

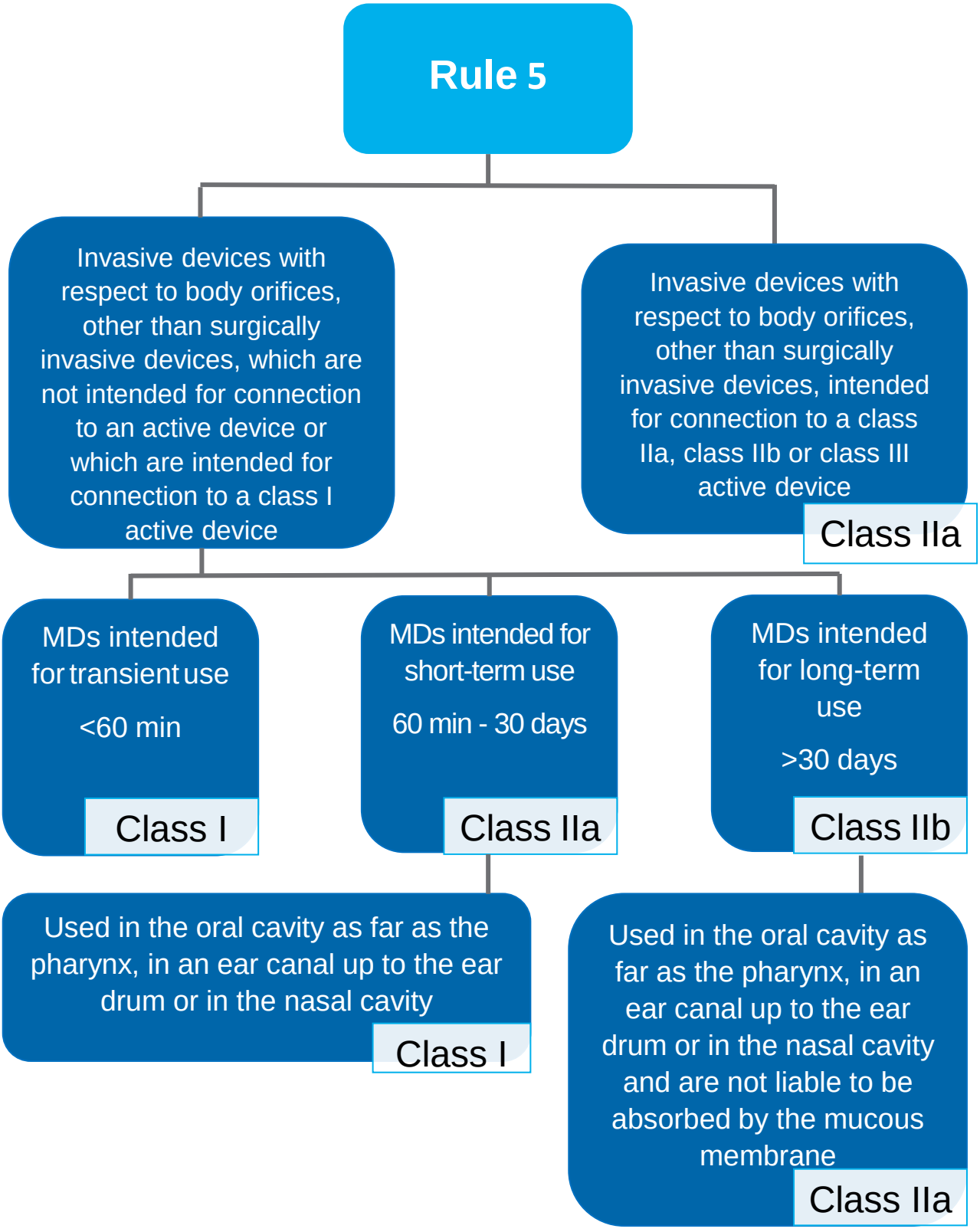
Class IIa

Non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body

Class III


Rule 4
Non-invasive devices which come into contact with injured skin or mucous membrane
Invasive devices which come into contact with injured mucous membrane
MDs intended to be used as a mechanical barrier, for compression or for absorption of exudates
Class I
MDs principally intended to manage the micro-environment of injured skin or mucous membrane
Class IIa
MDs intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent
Class IIb
All other cases
Class IIa

INVASIVE DEVICES



Rule 6

- Surgically invasive devices intended for transient use
  - <60 min → Class IIa
- MDs intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body → Class III
- Reusable surgical instruments → Class I
- MDs intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system → Class III
- MDs intended to supply energy in the form of ionizing radiation → Class IIb
- MDs which have a biological effect or are wholly or mainly absorbed → Class IIb
- MDs intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application → Class IIb

Rule 7

- Surgically invasive devices intended for short-term use
  60 min - 30 days
  Class IIa
- MDs specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body
  Class III
- MDs intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system
  Class III
- MDs intended to supply energy in the form of ionizing radiation
  Class IIb
- MDs which have a biological effect or are wholly or mainly absorbed
  Class III
- MDs intended to undergo chemical change in the body, except if the devices are placed in the teeth
  Class IIb
- MDs intended to administer medicines
  Class IIb

Rule 8

Implantabilní a dlouhodobé chirurgicky invazivní prostředky
>30 dnů — Class IIb

MDs intended to be placed in the teeth — Class IIa

MDs intended to be used in direct contact with the heart, the central circulatory system or the central nervous system — Class III

MDs which have a biological effect or are wholly or mainly absorbed — Class III

MDs intended to undergo chemical change in the body, except if the devices are placed in the teeth — Class III

MDs intended to administer medicinal products — Class III

Active implantable devices or their accessories — Class III

Breast implants or surgical meshes — Class III

Total or partial joint replacements — Class III

Spinal disc replacement implants or implantable devices that come into contact with the spinal column, with the exception of components such as screws, wedges, plates and instruments — Class III

ACTIVE DEVICES

Rule 9

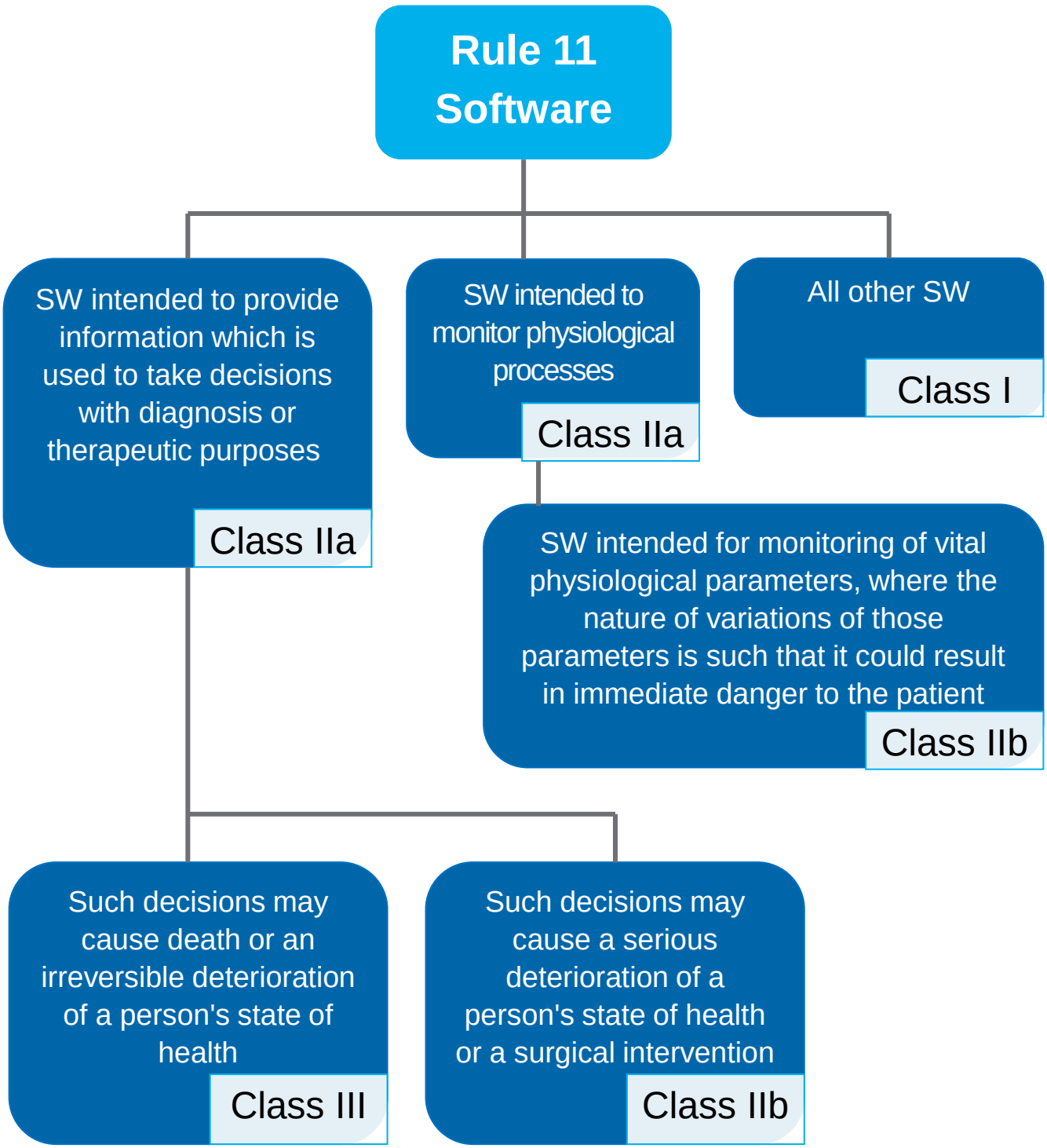
- Active therapeutic devices intended to administer or exchange energy — Class IIa
  - MD's characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy — Class IIb
- Active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices — Class IIb
- Active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance — Class IIb
- Active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices — Class III

Rule 10

Active devices intended for diagnosis and monitoring

- MDs intended to supply energy which will be absorbed by the human body — Class IIa
- MDs intended to illuminate the patient's body, in the visible spectrum — Class I
- MDs intended to image in vivo distribution of radiopharmaceuticals — Class IIa
- MDs intended to allow direct diagnosis or monitoring of vital physiological processes — Class IIa
- MDs specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient — Class IIb

Active devices designed to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices that control or monitor such devices or directly affect their effectiveness — Class IIb


Rule 11
Software
SW intended to provide information which is used to take decisions with diagnosis or therapeutic purposes
Class IIa
SW intended to monitor physiological processes
Class IIa
All other SW
Class I
SW intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient
Class IIb
Such decisions may cause death or an irreversible deterioration of a person's state of health
Class III
Such decisions may cause a serious deterioration of a person's state of health or a surgical intervention
Class IIb

Rule 12

Active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body

Class IIa

Active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body, in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application

Class IIb

Rule 13

All other active devices

Class I

SPECIAL RULES

Rule 14

MDs incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices

Class III

Rule 15

MDs used for contraception or prevention of the transmission of sexually transmitted diseases

Class IIb

Implantable or long term invasive devices

Class III

Rule 16

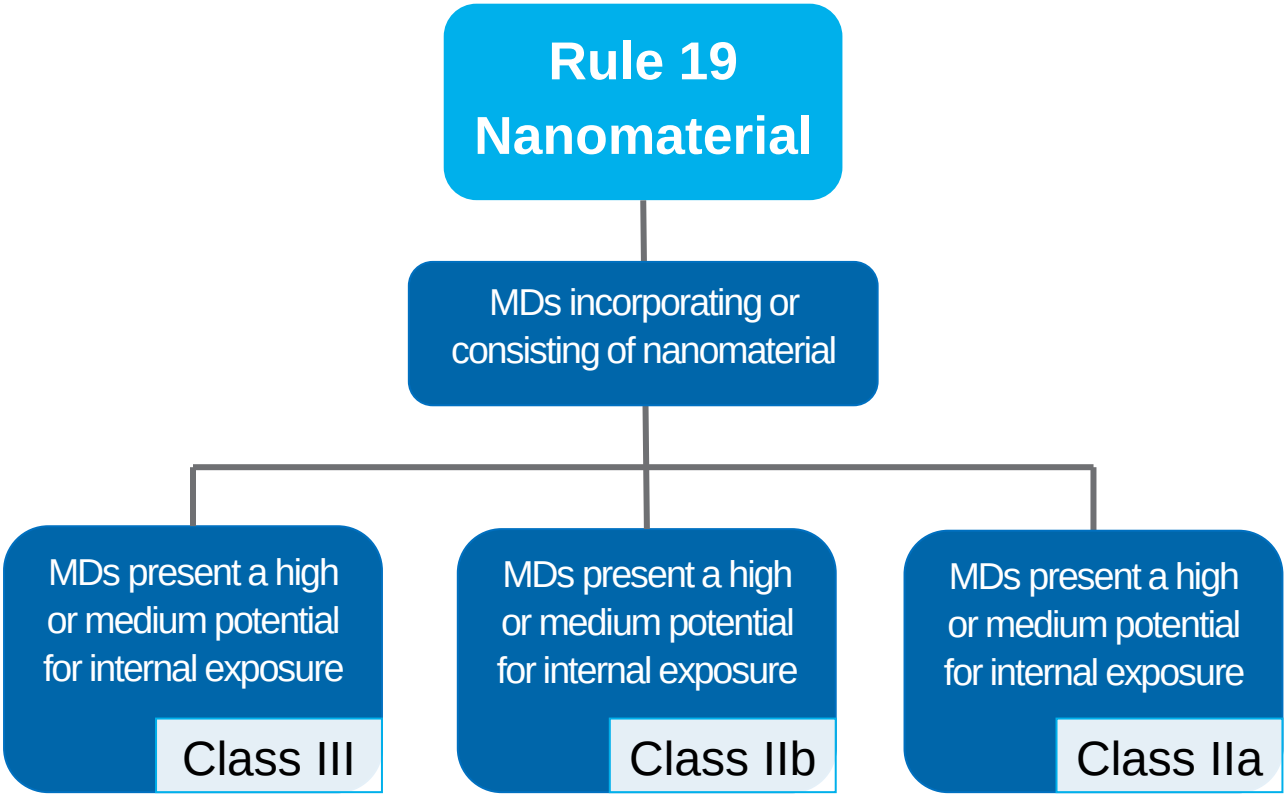
- MDs intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses — Class IIb
- MDs intended specifically to be used for disinfecting or sterilising medical device — Class IIa
  - Disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing — Class IIb
- MDs intended to clean devices other than contact lenses by means of physical action only — This rule does not apply

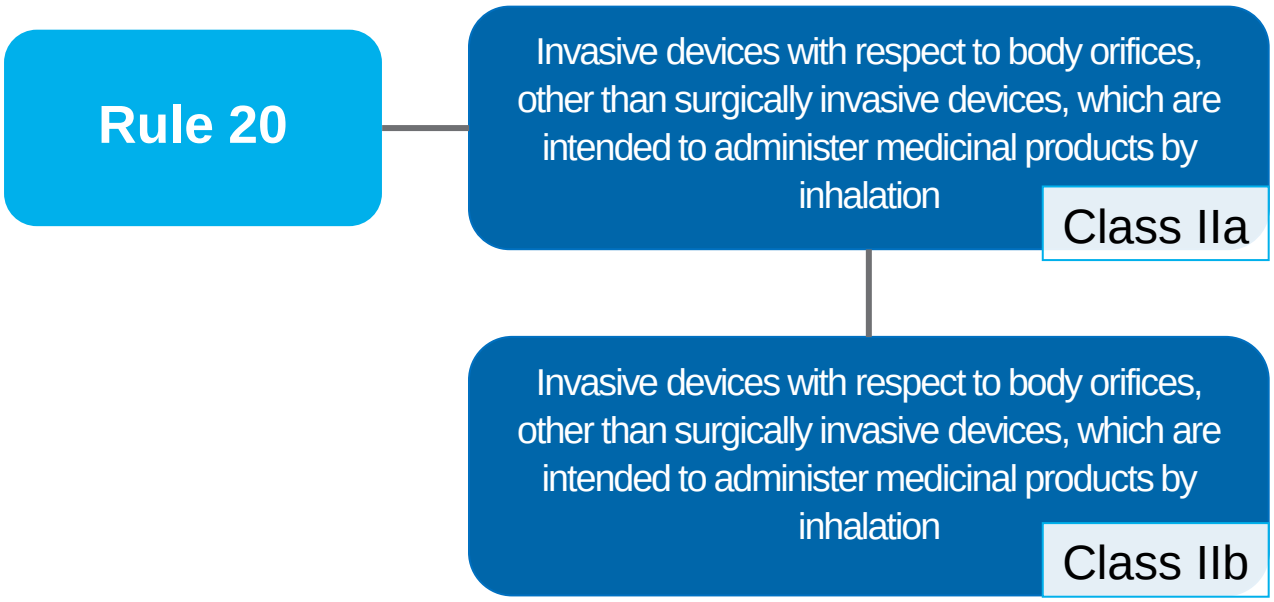
Rule 17

MDs specifically intended for recording of diagnostic images generated by X-ray radiation — Class IIa

Rule 18

MDs manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are not intended to come into contact with intact skin only, or manufactured utilising tissues or cells of human origin, or their derivatives, which are non-viable or rendered non-viable — Class III

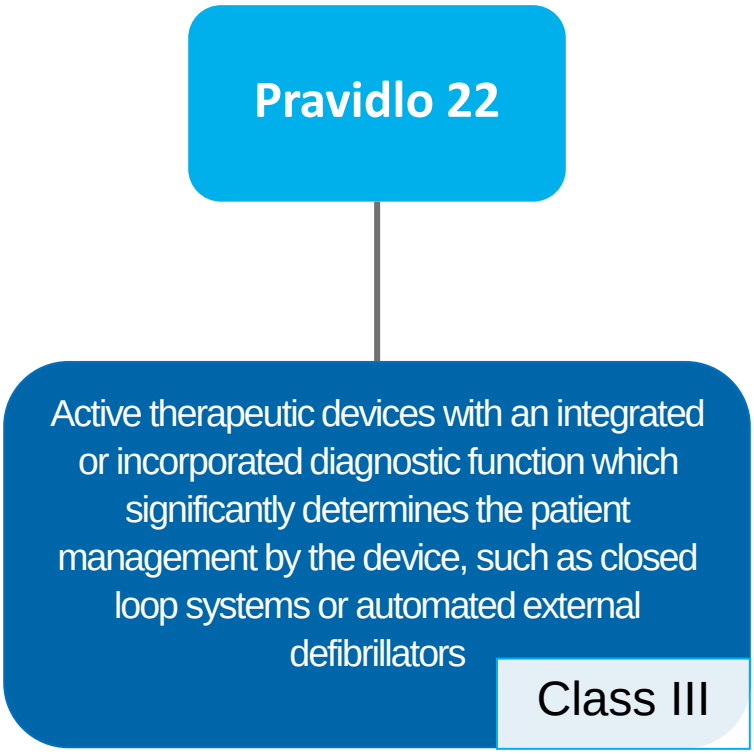

Rule 19
Nanomaterial
MDs incorporating or consisting of nanomaterial
MDs present a high or medium potential for internal exposure
Class III
MDs present a high or medium potential for internal exposure
Class IIb
MDs present a high or medium potential for internal exposure
Class IIa


Rule 20
Invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation
Class IIa
Invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation
Class IIb

Rule 21

Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body

- MDs or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose — **Class III**
- MDs achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body — **Class III**
- MDs are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities — **Class IIa**
- All other cases — **Class IIb**


Pravidlo 22
Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators
Class III

4. RULES FOR THE SELECTION OF CONFORMITY ASSESSMENT PROCEDURE

Before placing a medical device on the market, an assessment of compliance with the requirements of the MDR is required. The MDR defines three basic conformity assessment procedures (Annex IX, X and XI MDR). The use of each procedure, or a combination of them, depends on the risk class of the device (Article 52 MDR).

4.1 Helpful Terms

It is useful to be familiar with the terms you may encounter when selecting a conformity assessment procedure:

Generic device group

A set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

Device category

First level of the European Nomenclature of Medical Devices (see MDCG 2021-12).

Implantable MD class IIb WET (well-established technologies)

Devices listed in the second paragraph Article 52 (4) MDR, that is sewing material, staples and clamps, dental fillings and crowns, braces, screws, wedges, plates, wires, pins, clips and connectors.

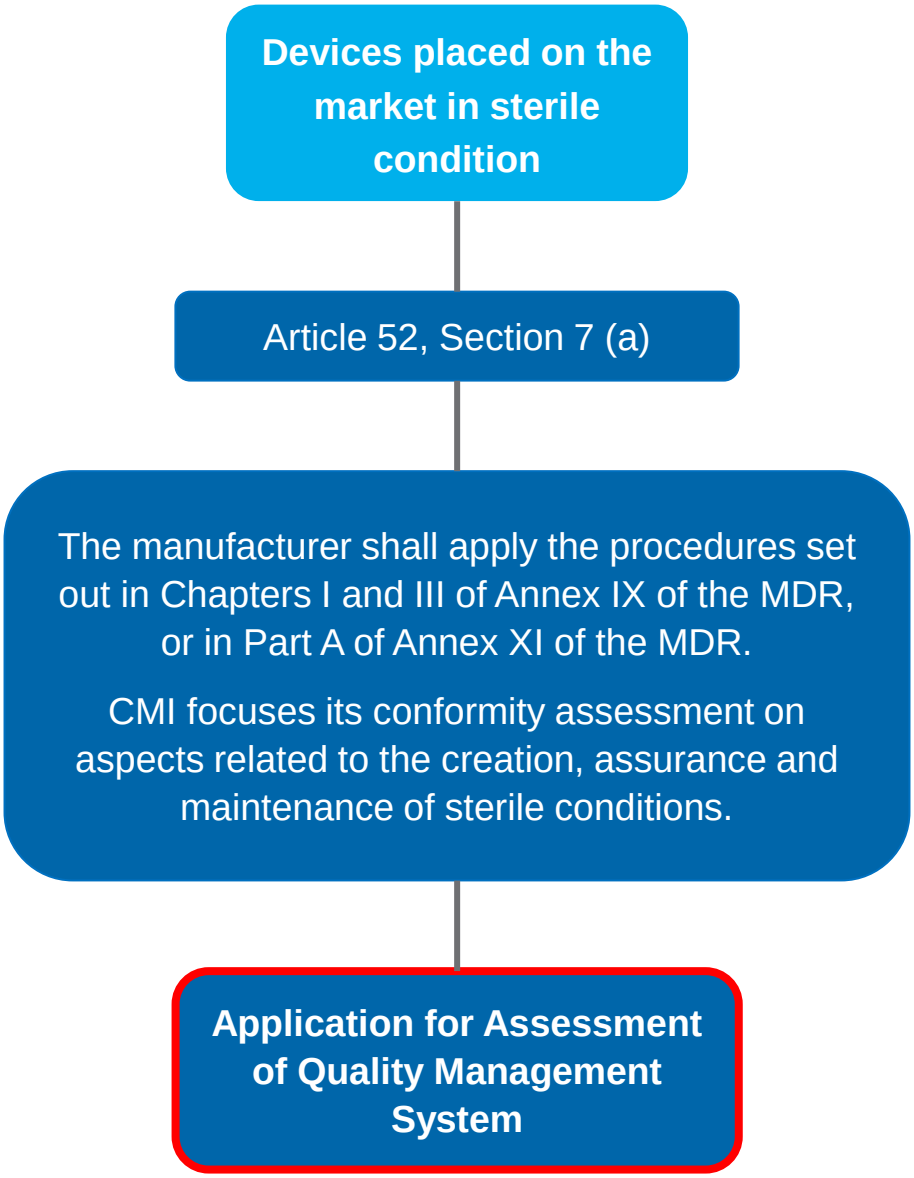
Im – class I devices with a measuring function (MDCG 2019-15)

Is – class I devices in a sterile state (viz MDCG 2019-15)

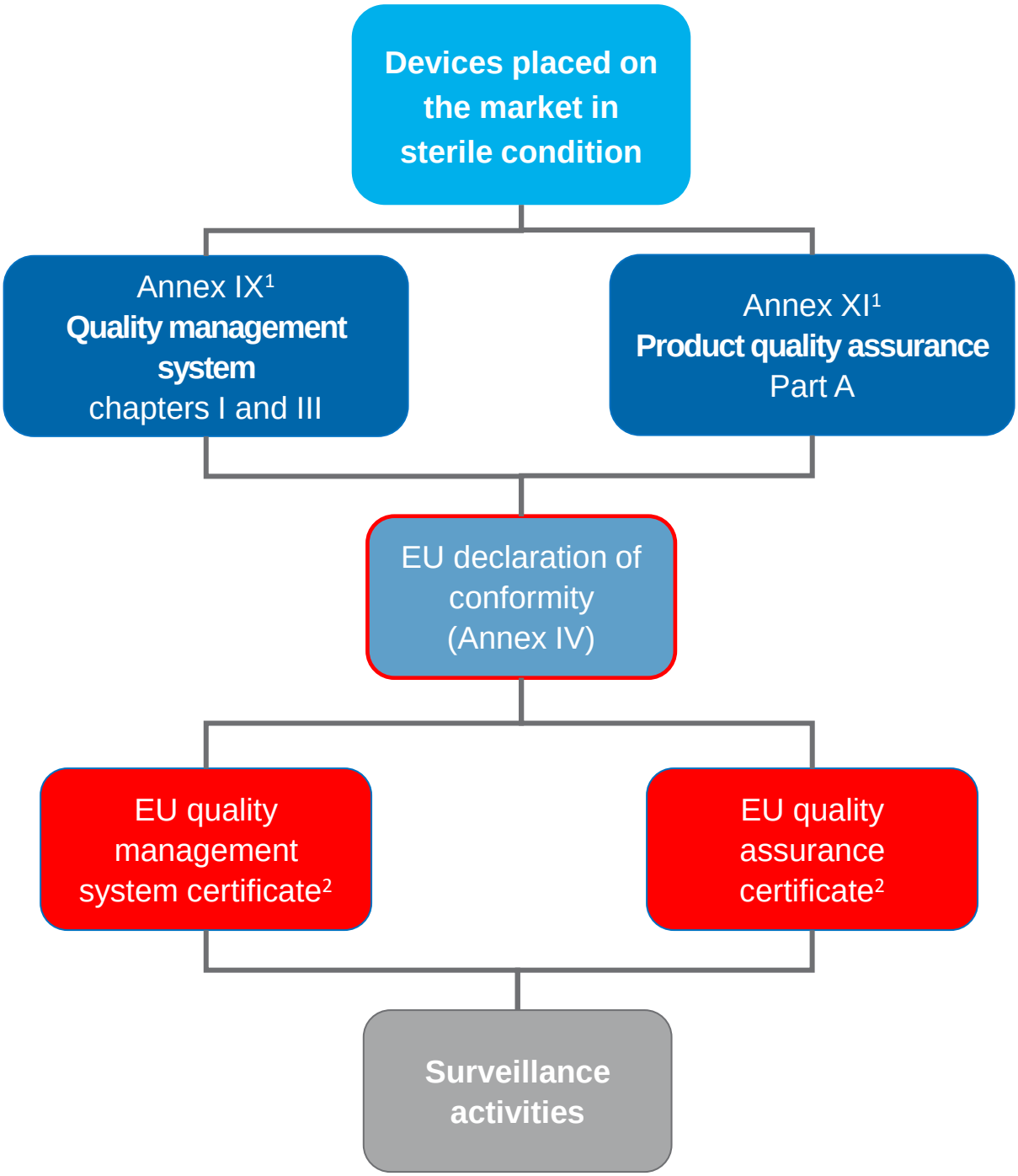
Ir – class I devices that are reusable chirurgic instruments (MDCG 2019-15)

4.2 Conformity Assessment Procedures

Risk Class Is



Risk Class Is



1 The powers of the notified body are limited to the assessment and audit of sterility-related aspects.

2 Certificates are limited to the quality management system or quality assurance related to sterility aspects

Risk Class Im

Devices with a measuring function

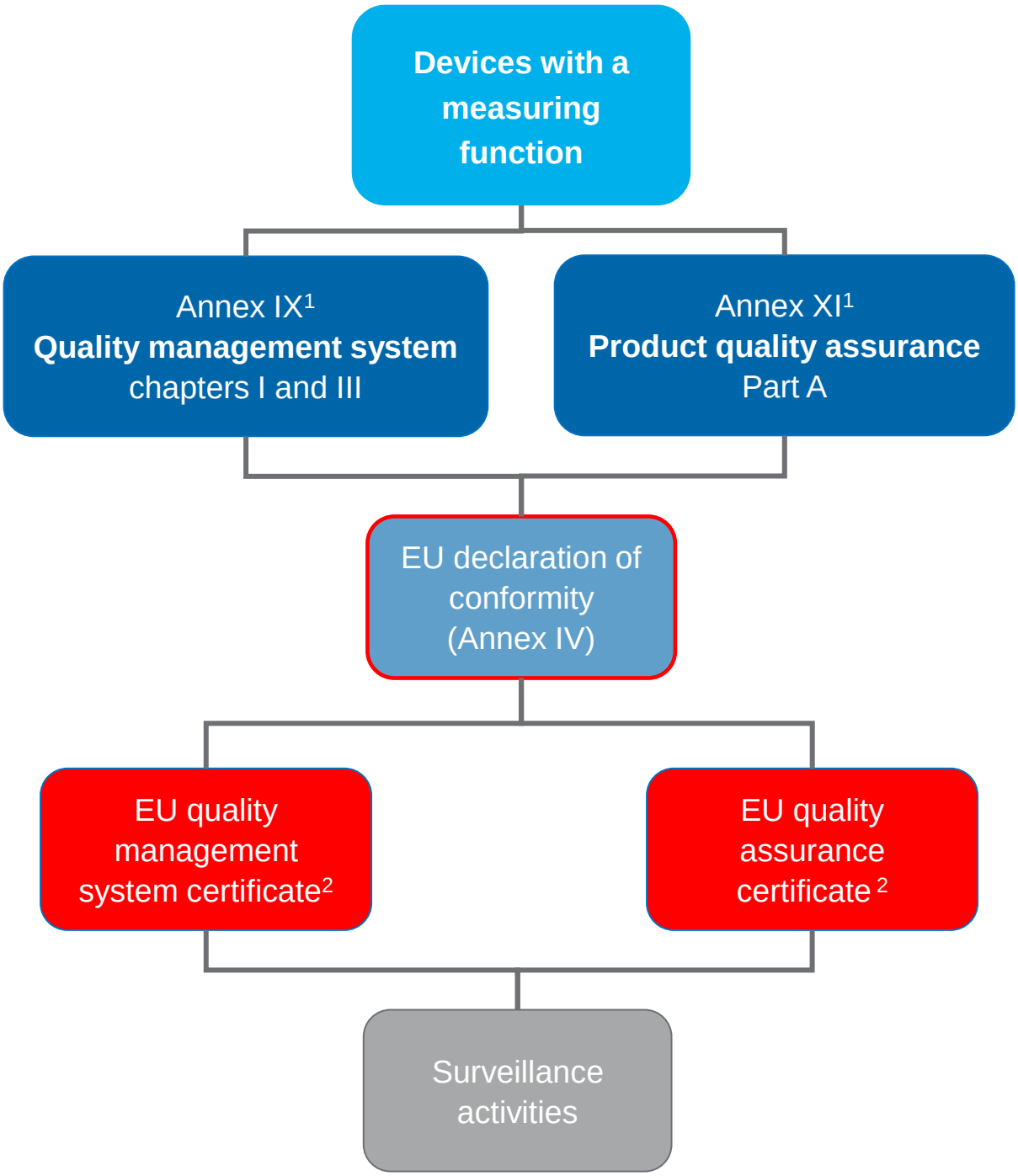
Article 52, Section 7 (b)

The manufacturer shall apply the procedures set out in Chapters I and III of Annex IX of the MDR, or in Part A of Annex XI of the MDR.

CMI focuses its conformity assessment on aspects related to the compliance of devices with metrological requirements.

Application for Assessment of Quality Management System

Risk Class Im



1 The powers of the notified body are limited to the assessment and audit of aspects related to metrology

2 Certificates are limited to the quality management system or quality assurance related to metrology aspects

Risk Class Ir

Reusable surgical instruments

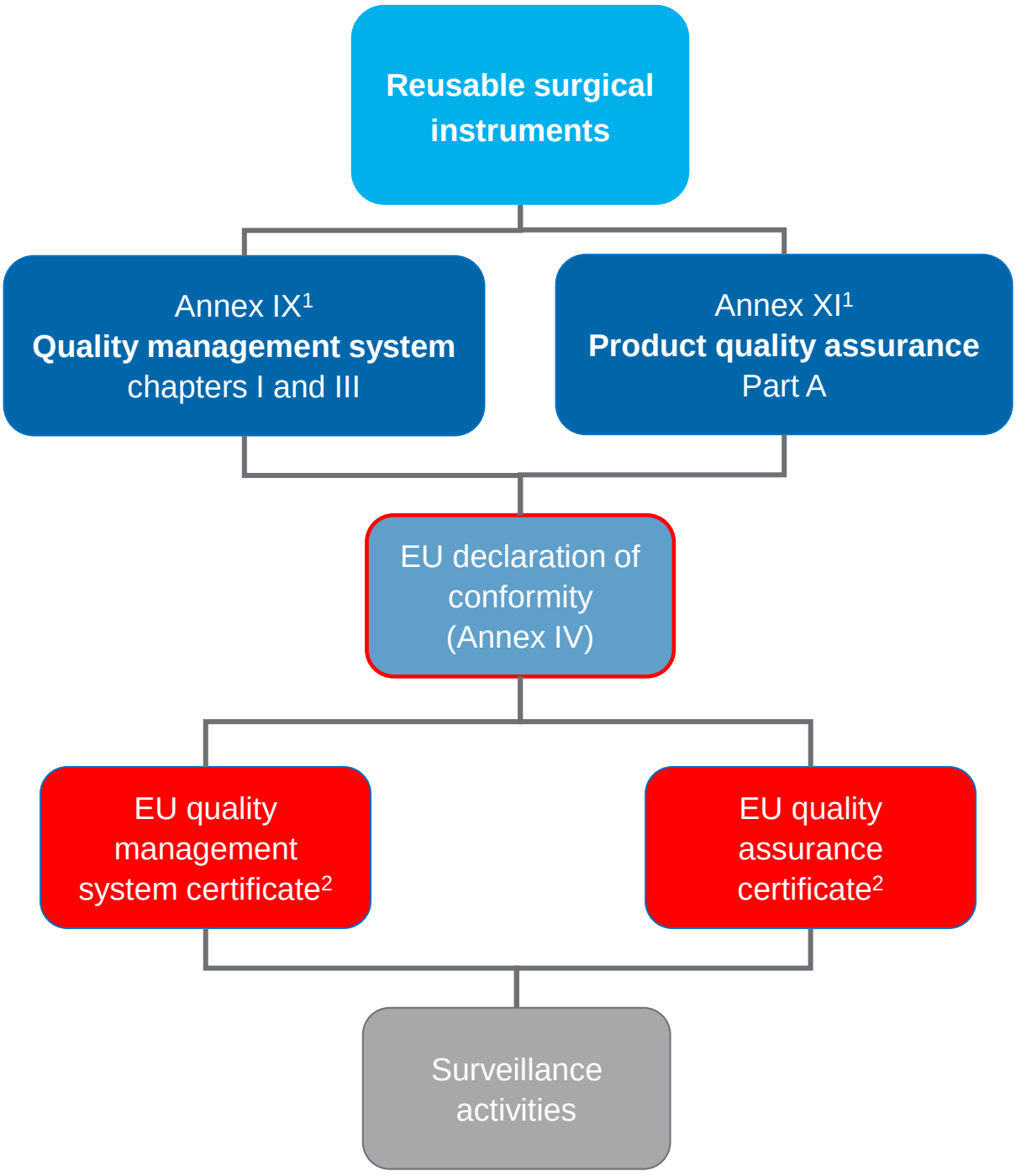
Article 52, Section 7 (c)

The manufacturer shall apply the procedures set out in Chapters I and III of Annex IX of the MDR, or in Part A of Annex XI of the MDR.

CMI focuses its conformity assessment on aspects related to the reusability of the device, such as in particular cleaning, disinfection, sterilisation, maintenance and control activities and related instructions for use.

Application for Assessment of Quality Management System

Risk Class Ir



1 The powers of the notified body are limited to the assessment and audit of aspects related to the reusability of surgical instruments (cleaning, sterilisation).
2 Certificates are limited to quality management system or quality assurance related to the reusability of surgical instruments aspects.

Risk Class IIa

Class IIa devices

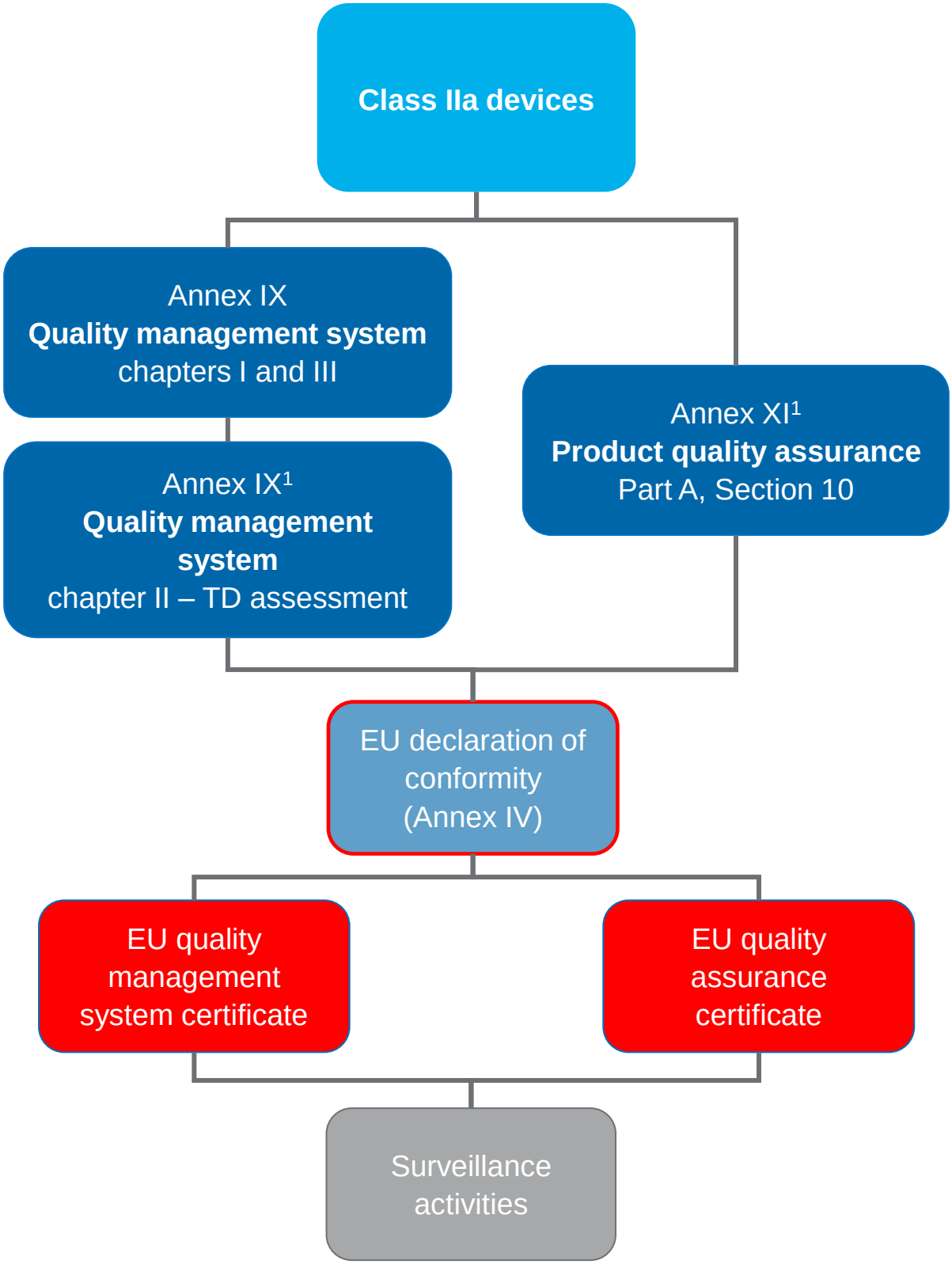
Article 52, Section 6

The manufacturer shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX of the MDR, and including an assessment of the technical documentation as specified in Section 4 of the Annex of at least one representative device for each category of devices.

The manufacturer may choose to draw up the technical documentation coupled with a conformity assessment as specified in Section 10 of Annex XI of the MDR.

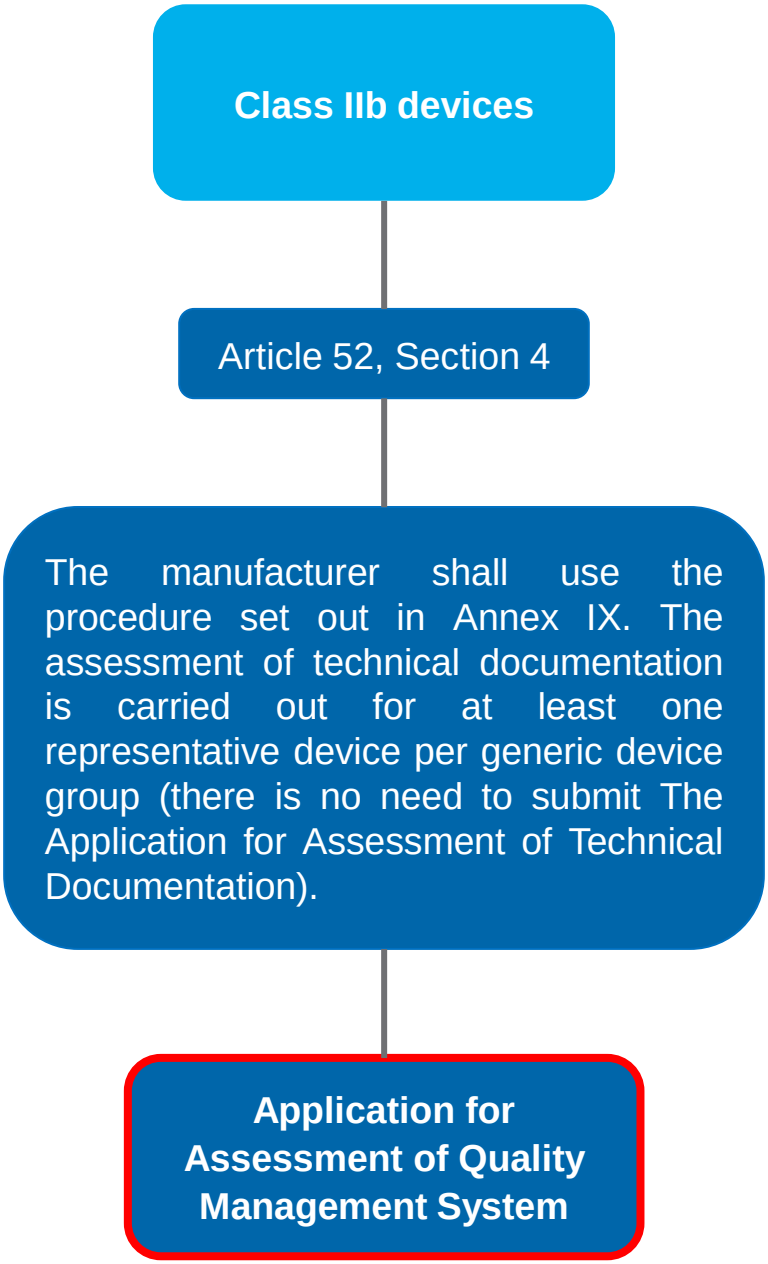
Application for Assessment of Quality Management System

Risk Class IIa

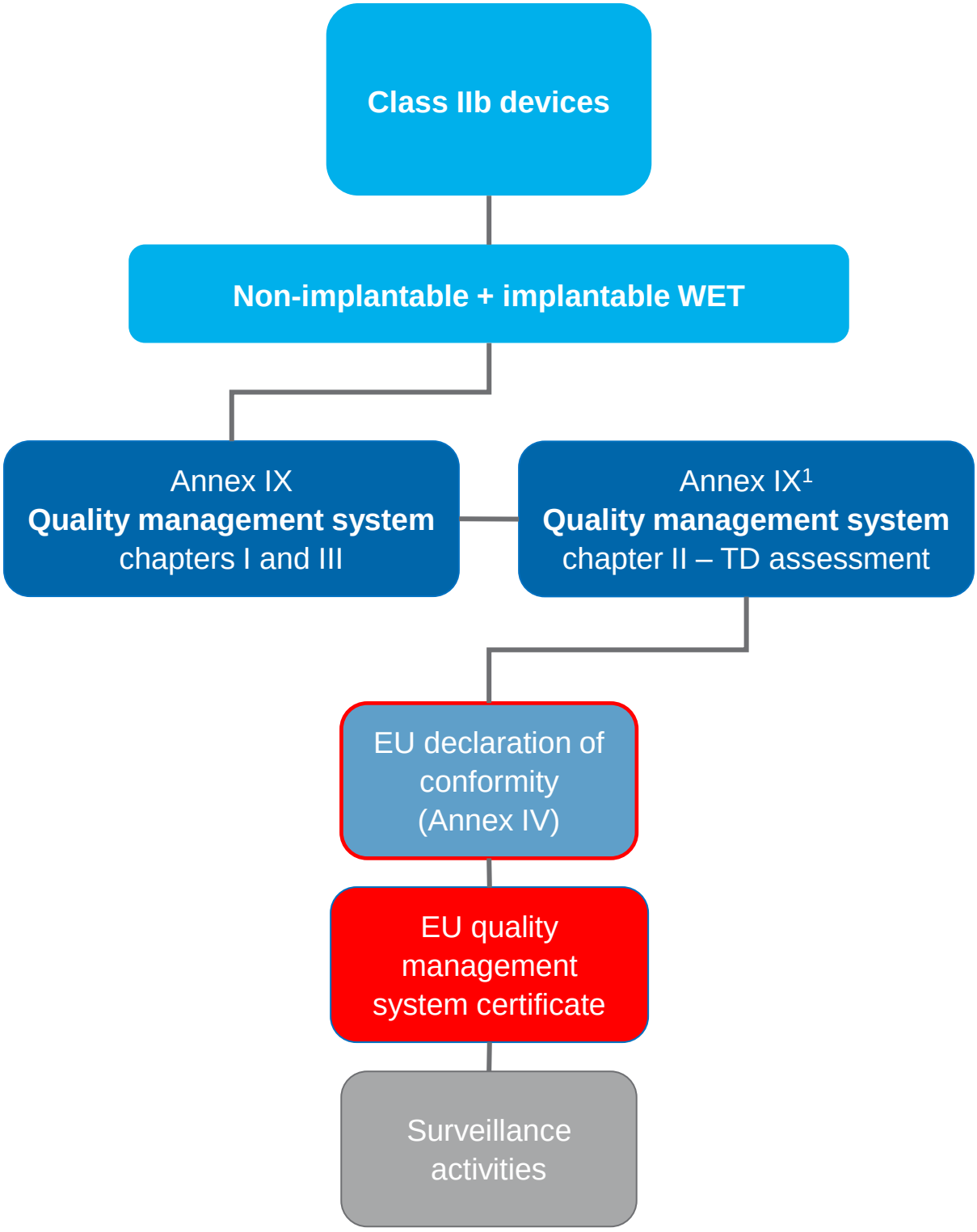


1The assessment of the technical documentation shall apply for at least one representative device for each category of devices

Risk Class IIb Non-implantable + Implantable WET

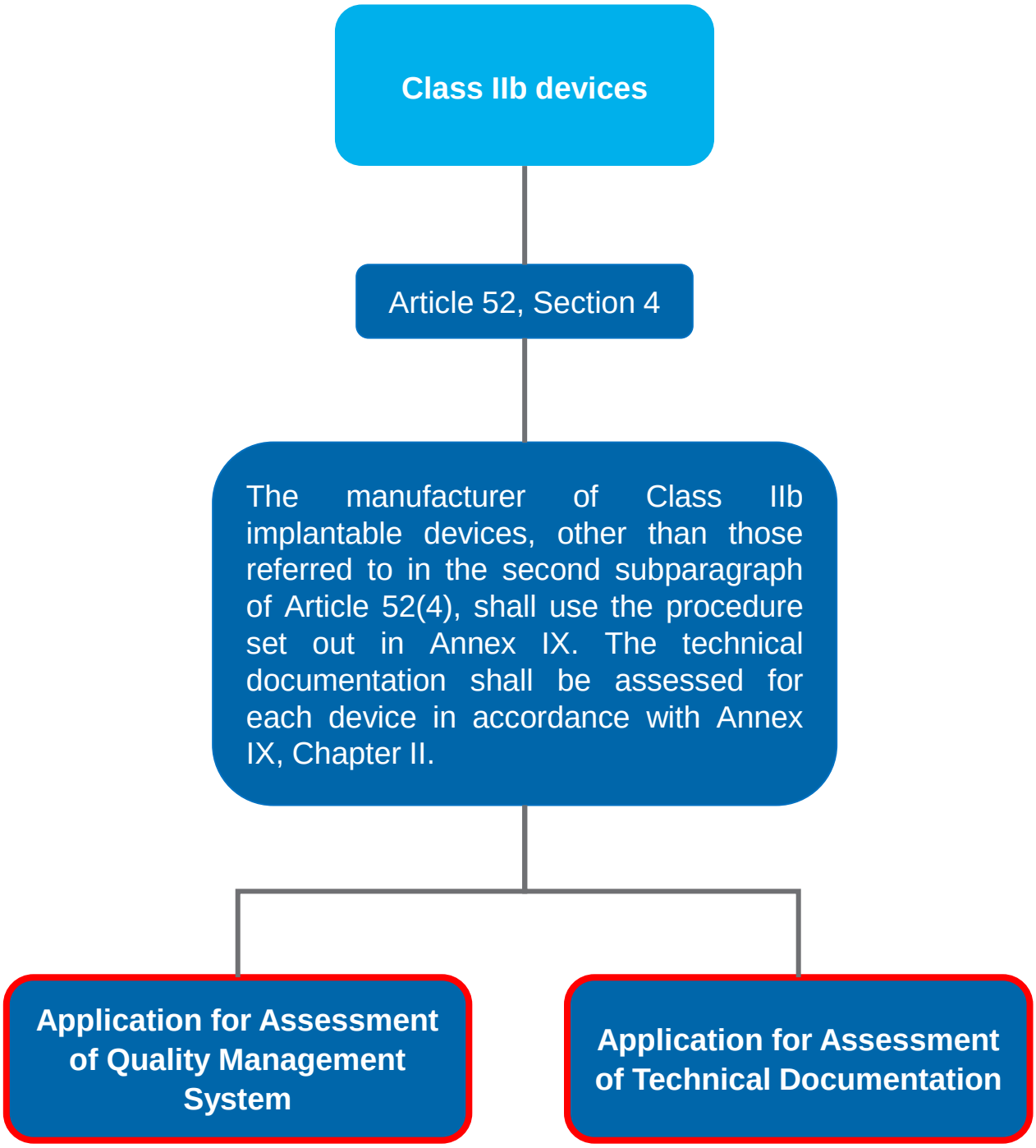


Risk Class IIb Non-implantable + Implantable WET

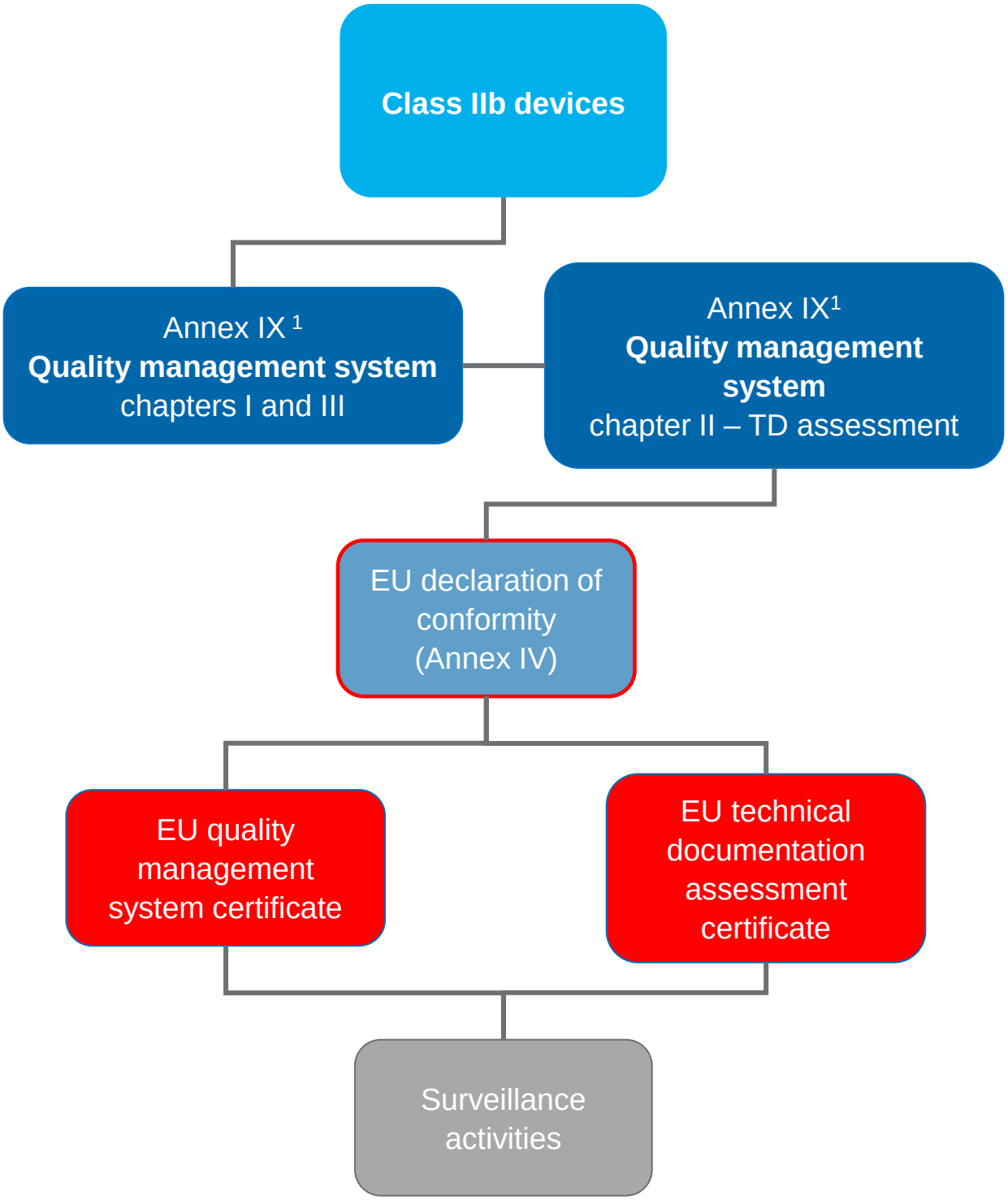


1The assessment of the technical documentation shall apply for at least one representative device for each category of devices

Risk Class IIb Implantable



Risk Class IIb Implantable



1 Assessment of the technical documentation will be carried out for each device

5. QUALITY MANAGMENT SYSTEM

A quality management system includes all elements of your company that relate to the quality of processes, procedures and resources. It controls the structure, obligations, processes and management recourses required for the application of the principles and implementation necessary to comply with the MDR and other legislation.

All elements, requirements and legislation used for the application of the quality management system should be systematically and orderly documented in the form of a quality manual of documented procedures or quality programs, quality plans and quality records.

The MDR defines the requirements of the quality management system in Article 10 (Section 9) and Annex IX (Sections 2.1 and 2.2)

5.1 Requirements for Quality Management System Documentation

For compliance with the MDR it is necessary, that the quality management system reflects the following aspects:

a) A strategy of regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the devices covered by the system.

- a written declaration, that no other application for the same quality management system was field under a different notified body, or information about any previously field applications for the same quality management system relating to the device.
- documentation related to the manufacturer‘s system in quality management.
- description of goals, if they aim for quality.
- information about the device or a group of devices, that the quality management system is applied to.
- procedures established for the purpose of fulfilling the requirements of the quality management system according to the MDR, as well as a liability for the use of these procedures.
- procedures established for the purpose of maintaining the quality management system in a reasonable and effective state, as well as a liability for the use of these procedures.
- procedures for determining the relevant legislation requirements, qualification and classification, addressing equality issues, chaise of the conformity assessment procedure and their compliance.

b) Identification of applicable general safety and performance requirements and exploration of options to address those requirements.

- solutions aimed at complying with relevant safety and preformance requirements, taking into account applicable common specifications and harmonised standards or other appropriate solutions, if chosen.

c) Responsibility of the management.

- the name of the manufacturer and address of the registered place of business of the manufacturer and, if the application is lodged by the authorised representative, the name of the authorised representative and the address of its registered place of business.

d) Resource management, including selection and control of suppliers and sub-contractors.

- description of organisation structure with division of responsibilities between employees. In the case of critical procedures, the responsibility of employed managers and their organizational rights.
- a draft mandate for the nomination of the authorised representative and a letter of intent by the authorised representative to accept the mandate, if the manufacturer does not have a registered place of business in any EU Member State.
- description of the methods of monitoring the effective operation of the quality management system, and in particular the type and extent of control exercised over the third party when that party carries out the design, manufacture and/or final verification and testing of the devices or any part of the procedures.

e) Risk management as set out in Section 3 of Annex I.

f) Clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF.

- documentation on the clinical evaluation plan.
- PMCF plan.
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance, as well as the undertaking by the manufacturer to apply those procedures.

g) Product realisation, including planning, design, development, production and service provision.

- a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure.
- solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I.
- solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I.
- the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture.
- a description of the methods of verification and quality assurance during the manufacturing phase and, in particular, the processes and procedures to be used regards sterilisation.
- the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

g) Verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29.

h) Setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83.

- the documentation on the manufacturer's post-market surveillance system.
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan,, as well as the undertaking by the manufacturer to apply those procedures.

g) Handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders.

h) Processes for reporting of serious incidents and field safety corrective actions in the context of vigilance.

- a description of the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures.

g) Management of corrective and preventive actions and verification of their effectiveness.

g) processes for monitoring and measurement of output, data analysis and product improvement.

- the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform.
- the description of the procedures and techniques for monitoring, verification, validation and design control of devices and the corresponding documentation, as well as the data and records resulting from those procedures and techniques.

  Specifically, these procedures and techniques include:

  - a strategy for regulatory compliance, including procedures for identifying the relevant legislation requirements, qualification, classification, chaise of the conformity assessment procedure and their compliance.
  - identification of relevant general safety and performance requirements and solutions aimed at complying with those requirements, taking into account applicable common specifications and harmonised standards or other appropriate solutions, if chosen.
  - risk management as set out in Section 3 of Annex I.
  - clinical evaluation in accordance with Article 61 and Annex XIV, including post-market clinical follow-up.

- solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I.
- solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I.
- the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture.
- management of design or quality management system changes.

6. REQUIREMENTS FOR TECHNICAL DOCUMENTATION STRUCTURE

The technical documentation enables the assessment of the conformity of the device with the MDR requirements. It should therefore be in a clear, transparent and unambiguous form allowing easy navigation.

In terms of content and structure, it is advisable to comply with Annexes II and III of the MDR when creating the technical documentation, while meeting the relevant requirements of Annex I of the MDR.

In the table below you will find all the areas that the technical documentation should address.

Requirements	Note
1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1. Device description and specification	The device description should indicate the key features and different device variants. The differences between the variants should be clear. It's advised to supplement the description with figures and diagrams showing the design features and intended purposes of the device.
a) product or trade name and a general description of the device including its intended purpose and intended users	Ensure consistency of the medical devices names throughout the technical documentation.

Requirements	Note
b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability	
c) the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings	Indications and contraindications should be supported by objective evidence (e. g. based on risk analysis or clinical evaluation)
d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary	Description of the intended purpose, mechanism of action. Ensure that the description of the intended purpose is consistent throughout the technical documentation.
e) the rationale for the qualification of the product as a device	The justification for the qualification of the product must be based on the precise definition in the MDR.
f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII	The classification rules are described in Chapter 3 of this manual.
g) an explanation of any novel features;	Description of new features, both new to manufacturers and to the MD industry
h) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it	Give a brief description of the accessory and how it is used with the device.

Requirements	Note
i) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market	The description or list of variants should be supplemented with the relevant UDI-DI.
j) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams	
k) a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids	Description of the raw materials used in the key functional elements of the formulation, e.g. coatings, surface treatments, etc.
l) technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications	

Requirements	Note
1.2. Reference to previous and similar generations of the device	
a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;	
b) an overview of identified similar devices available on the Union or international markets, where such devices exist	
2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER	
A complete set of:	
the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold;	The label description should include all applicable levels of packaging. The description should be supplemented by label drawings, explanations of any symbols used, and a display of label placement, including label identification for sterile packaging. A check-list of the requirements of 23.2 or 23.3 of Annex I of the MDR may be included.
the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold	It is important that the information in the instructions for use is identical to that given in other parts of the technical documentation. It is appropriate to supplement the technical documentation with a checklist of the requirements of point 23.4 of Annex I of the MDR

Requirements	Note
3. DESIGN AND MANUFACTURING INFORMATION	
a) information to allow the design stages applied to the device to be understood	Describe the history of significant design changes, including trials performed.
b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation	
c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.	Describe the control of critical suppliers. The technical documentation should be supplemented by a quality agreement.
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR)	
The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:	
a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply	This point should be supplemented by a check-list with the individual GSPR requirements with notes on their fulfilment. This may include identification of documents documenting compliance with the requirements.
b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement	If the requirement is not applicable to the ZP, explain why.

Requirements	Note
c) the harmonised standards, CS or other solutions applied	
d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation	
5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT	
The documentation shall contain information on:	
a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I	According to the MDR, the benefit-risk ratio is understood as the ratio of benefits to the total residual risk. The analysis should be complemented by a comparison with a similar MD or similar treatment.
b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I	
6. PRODUCT VERIFICATION AND VALIDATION	
The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.	

Requirements	Note
6.1. Pre-clinical and clinical data	It is appropriate to divide this point into a section about pre-clinical data and a section about clinical data.
a) results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;	For the test results, please list all harmonised and non-harmonised standards, common specifications and other guidelines you have used.
b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:	
- the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user	The description should be supplemented by a bio-safety risk assessment. The nature and duration of contact with the patient's body should be taken into account when determining the tests. If any tests have not been performed, the decision must be justified.
- physical, chemical and microbiological characterisation	The description should be supplemented by product standards or material data sheets.

Requirements	Note
- electrical safety and electromagnetic compatibility	The description should be supplemented by test reports. If only some devices were tested as a representative sample/arrangement, add a description of how this sample/configuration can be considered representative of the other devices/arrangements.
- software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer)	It is advisable that the description of software verification and validation includes the development plan, requirements analysis, software architecture design, detailed software design, implementation and validation of software units, software integration, testing, release, risk analysis, cybersecurity documentation, etc. It is appropriate to supplement the technical documentation with a check-list of the requirements of EN 62304.
- stability, including shelf life	The shelf-life is the period of time the product can be kept in its packaging before first use. For devices placed on the market in a sterile state, it is appropriate to perform a stability study on the integrity of the packaging materials.
- performance and safety.	The description of efficacy and safety should include the design control matrix, design requirements, verification and validation plan, demonstration of device lifetime, test reports and test reports.

Requirements	Note
Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council (1) shall be demonstrated.	The referenced Directive concerns the application of the principles of good laboratory practice and the verification of their application in the testing of chemicals.
Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service	
c) the clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV	If the clinical evidence is based on the demonstration of equivalence, it is appropriate to complement the clinical evaluation with a description of the differences between the subject and the equivalent MD and their potential clinical impact. Do not forget to include qualified CVs of the persons conducting or approving the clinical trial.
d) the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable	Provide information on sales complaints, including sales outside the EU. Ensure that PMCF and PMS data is up to date.

Requirements	Note
6.2. Additional information required in specific cases	
a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product	Not within the scope of the CMI appointment.
b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives	Not within the scope of the CMI appointment.
c) devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body	Not within the scope of the CMI appointment.
d) devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body	Not within the scope of the CMI appointment.
e) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.	The description should be supplemented by the results of tests of the entire production process, including the integrity of the sterile packaging.

Requirements	Note
f) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.	It is advisable to supplement the technical documentation with test protocols for determining accuracy limits, calibration, etc.
g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.	The description should be supplemented with the results of manipulation tests that have verified the safety and efficacy of the MD combination.

7. HELPFUL REFERENCES

Czech Metrology Institute – Notified Body under MDR	https://www.cmi.cz/mdr
State Institute for Drug Control (SÚKL)	https://www.sukl.cz/
MDR	
English version	https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745
Czech version	https://eur-lex.europa.eu/legal-content/CS/TXT/HTML/?uri=CELEX:32017R0745
EUDAMED	
European Database for Medical Devices	https://ec.europa.eu/tools/eudamed/#/screen/home
Information Center – EUDAMED	https://webgate.ec.europa.eu/eudamed-help/en/welcome-to-the-eudamed-information-centre.html
MDCG documents	
English version	https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
Czech version	https://www.niszp.cz/doporucujici-pokyny-ek-cz

CMI MEDICAL
MEDICAL DEVICES CERTIFICATION CENTRE

Contact us

Do you require assistance or wish to verify if your medical device qualifies for assessment by CMI?
Do not hesitate to reach out to us:

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