CZECH METROLOGY INSTITUTE

Czech metrology institute
Notified Body No. 1383

Český metrologický institut
Oznámený subjekt č. 1383

ČESKÝ METROLOGICKÝ INSTITUT

Methodological guide

RULES FOR THE SELECTION OF CONFORMITY ASSESSMENT PROCEDURE

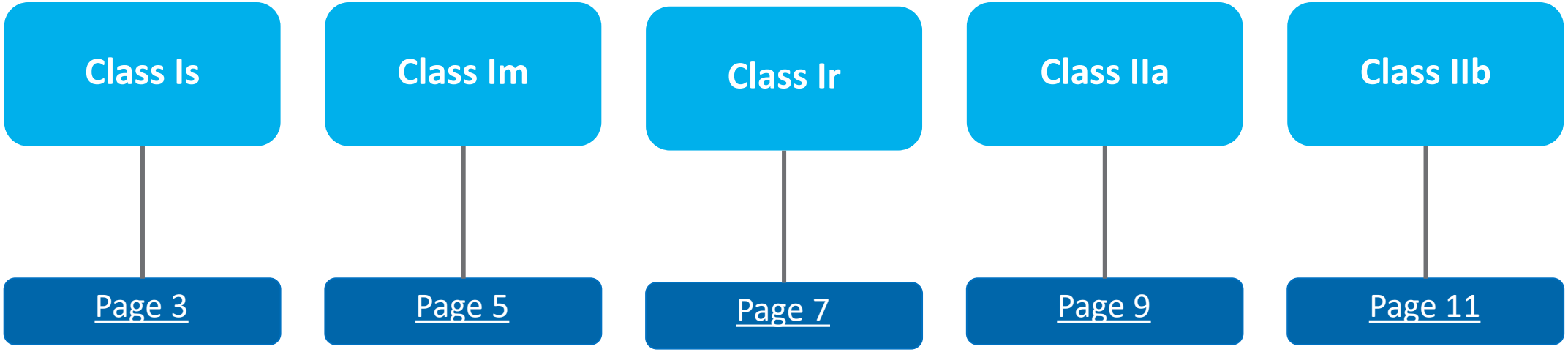
This methodological guide serves only as an aid to orientation in the issue of conformity assessment procedures for medical devices. We recommend using Article 52 of the MDR to determine the appropriate conformity assessment procedure for your medical device.

Verze 23-001

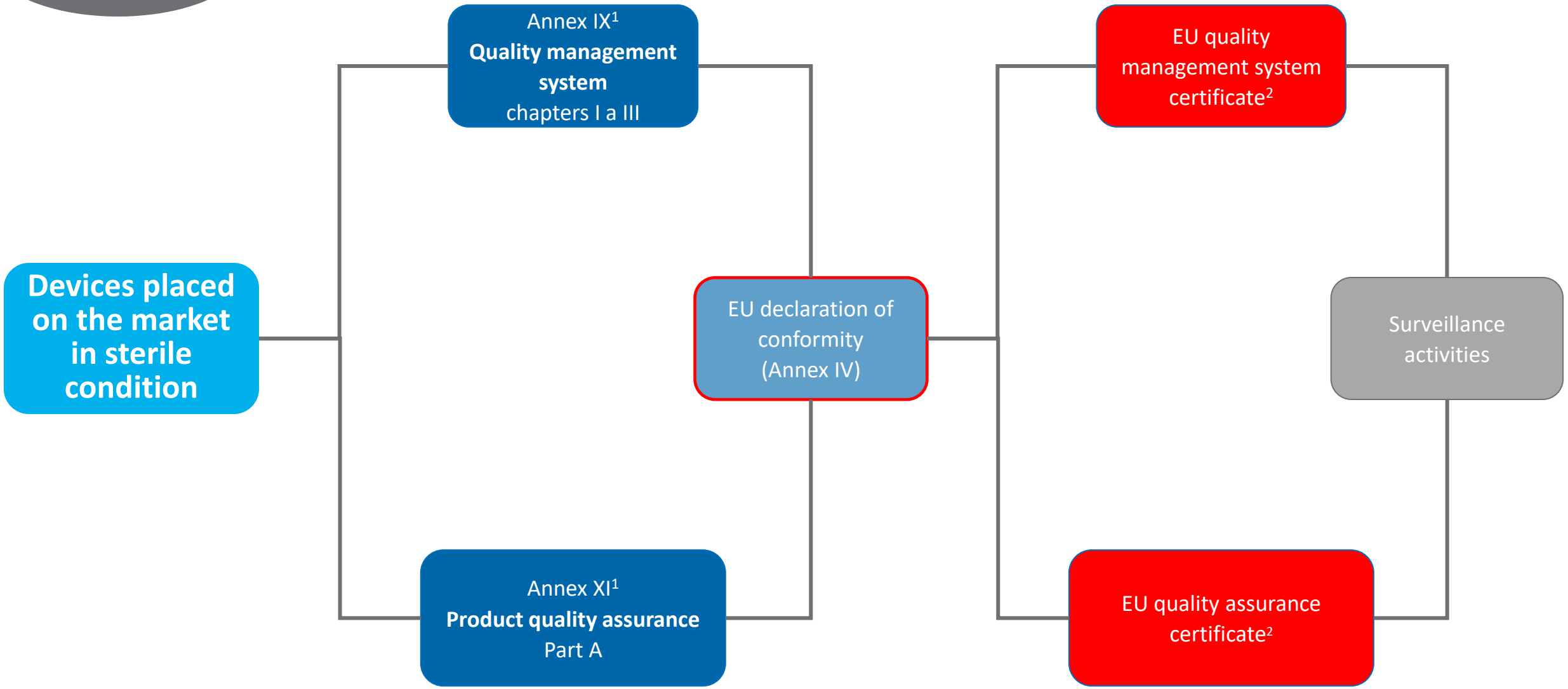
According to the MDR, five conformity assessment procedures can be used to carry out the medical device conformity assessment.

Article 52 of the MDR defines the possible variations and combinations of the application of conformity assessment procedures for each class of medical devices. The guide below provides an overview of the procedures that can be used for conformity assessment of medical devices if the services of the Czech Metrology Institute (within the scope of its notification) are used.

By following the link you can easily find out which of the listed procedures can be used for your medical device.



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

Class Is

Devices placed on the market in sterile condition

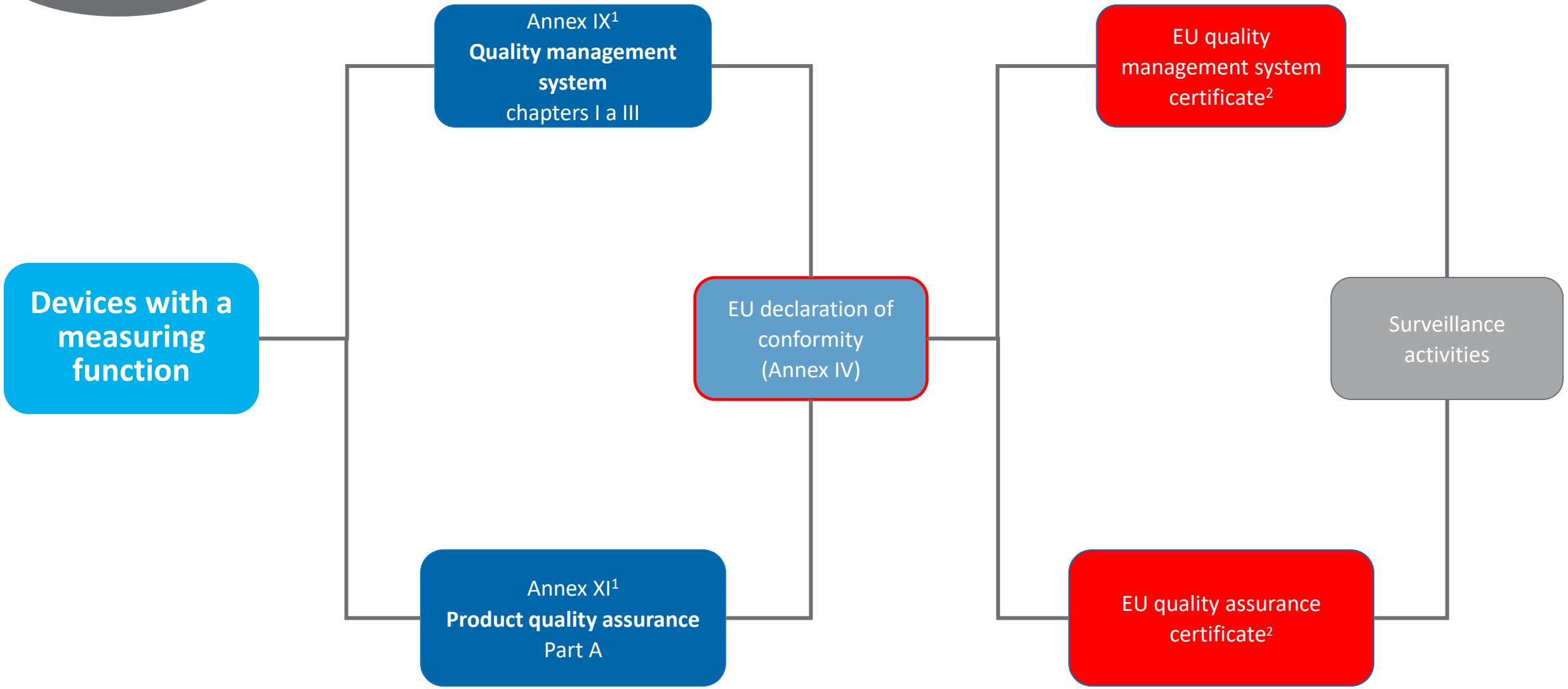
Article 52, Section 7 (a)

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 creation, assurance and maintenance of sterile conditions.

Application for Assessment of Quality Management System

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

Class Im

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Devices with a measuring function

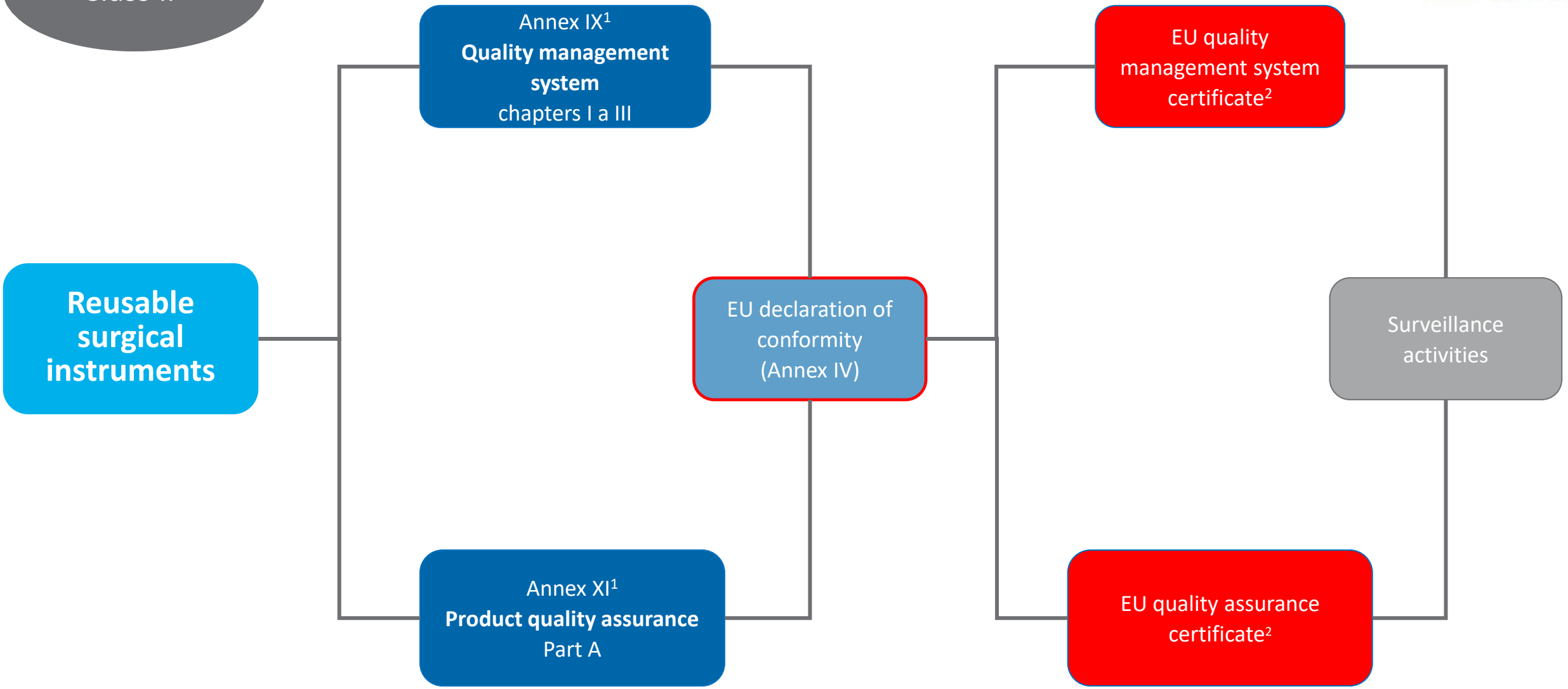
Article 52, Section 7 (b)

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

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

Class Ir

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Reusable surgical instruments

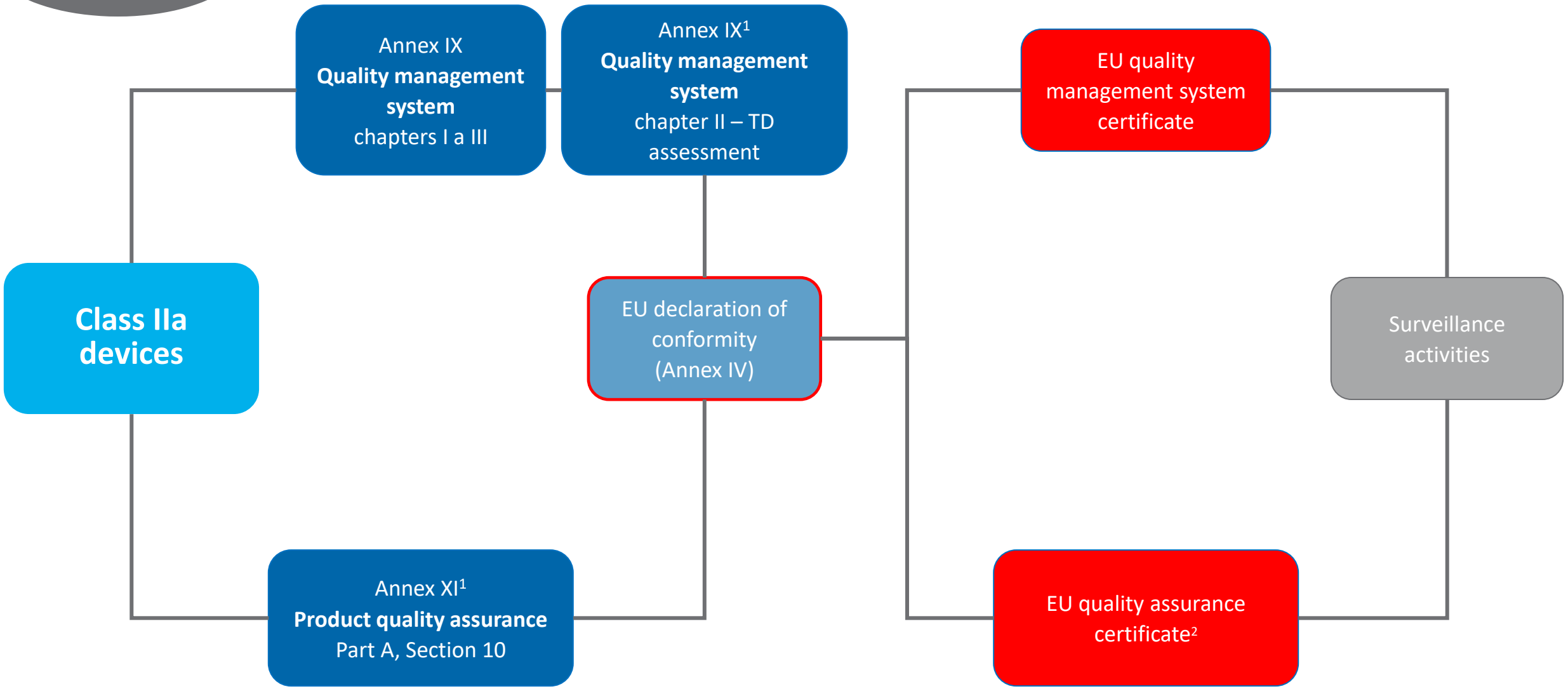
Article 52, Section 7 (c)

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

Class IIa



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

Class IIa

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Class IIa devices

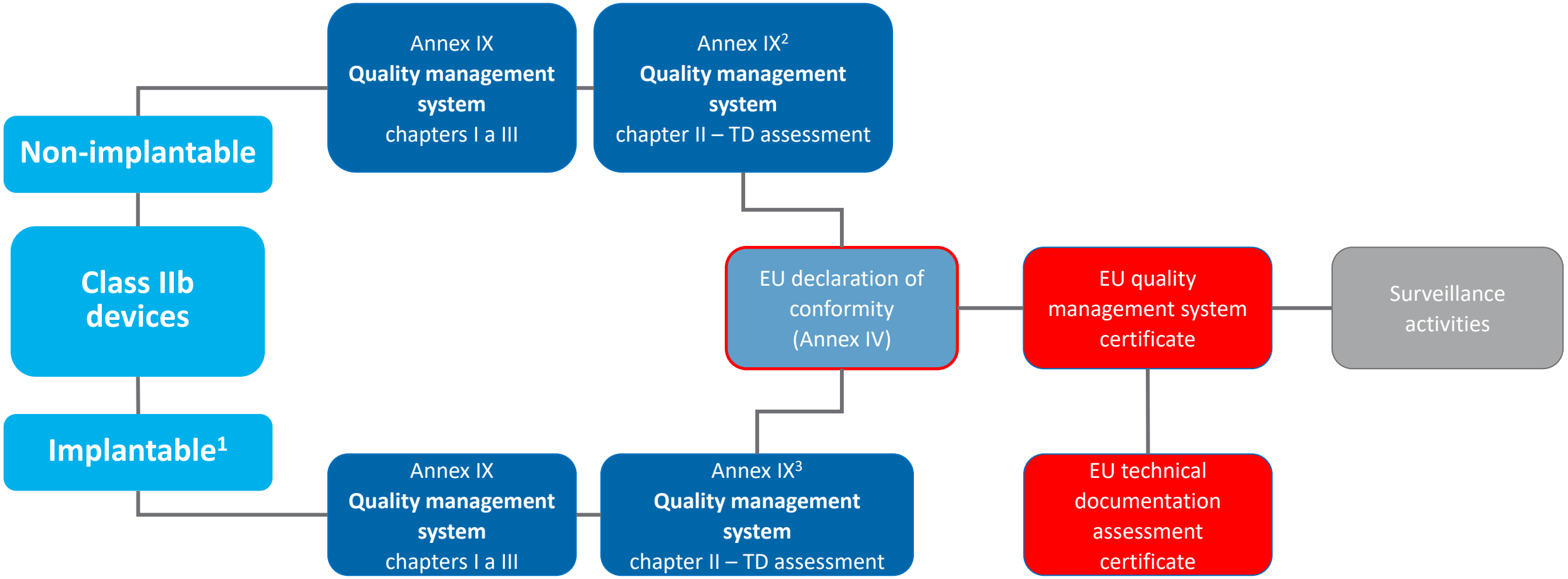
Article 52, Section 6

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

Class IIb

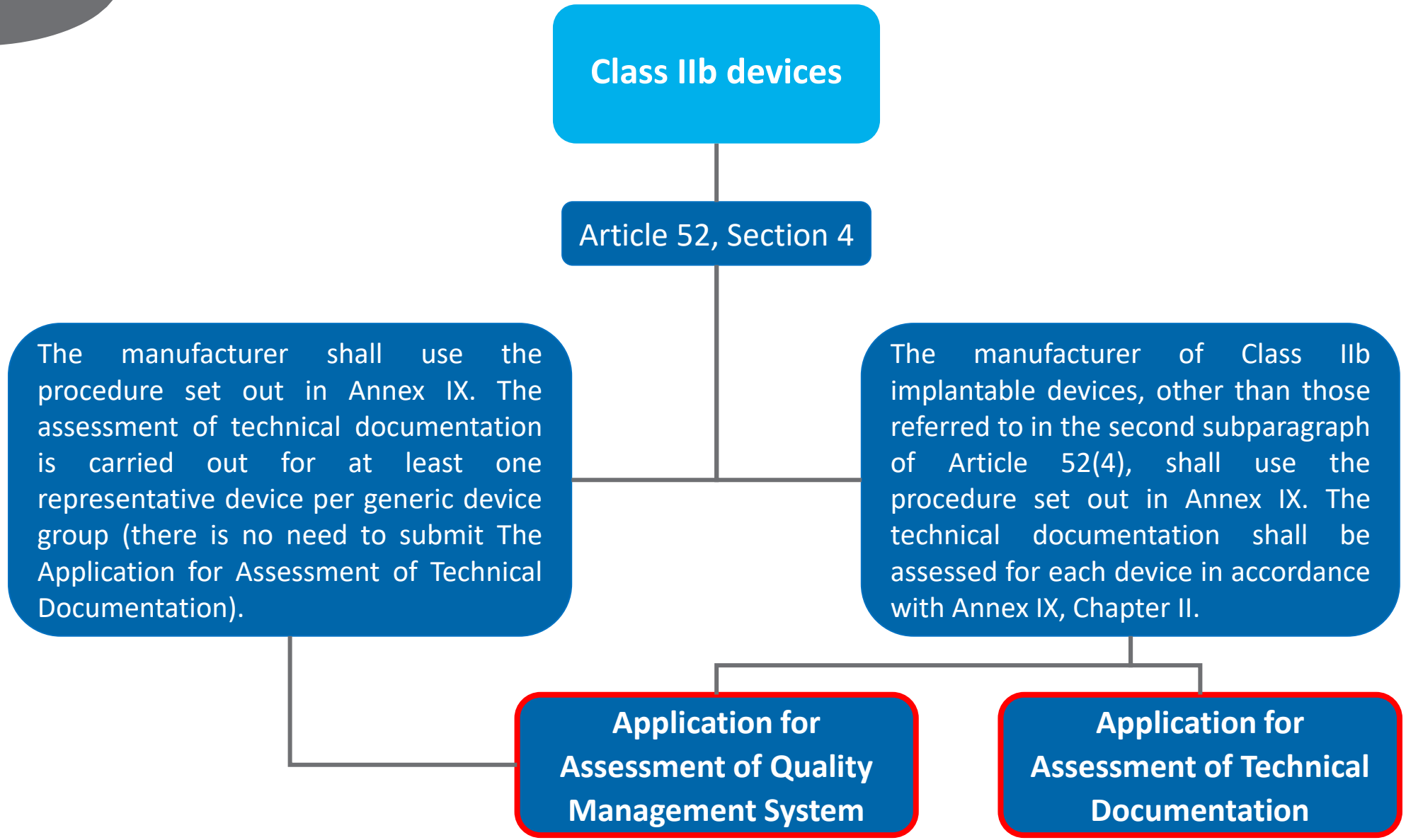


[1]Does not apply for class IIb implantable devices in well-established technologies, namely sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors (according to Article 52, Section 4)

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

[3]Assessment of the technical documentation will be carried out for each device

Class IIb


Class IIb devices
Article 52, Section 4
The manufacturer shall use the procedure set out in Annex IX. The assessment of technical documentation is carried out for at least one representative device per generic device group (there is no need to submit The Application for Assessment of Technical Documentation).
The manufacturer of Class IIb implantable devices, other than those referred to in the second subparagraph of Article 52(4), shall use the procedure set out in Annex IX. The technical documentation shall be assessed for each device in accordance with Annex IX, Chapter II.
Application for Assessment of Quality Management System
Application for Assessment of Technical Documentation