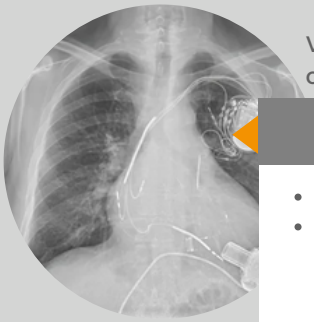
MDR DEADLINES BASED ON RISK FACTORS

GENERAL RULES



Validity
of the MDD certificate

31. 12. 2027.

- all class III devices
- class IIb implantable devices - except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

RISK CLASS

Validity
of the MDD certificate

31. 12. 2028.

- class IIb devices other than those covered by point above,
- class IIa devices,
- class I devices placed on the market
- oin sterile condition (Is)
- or having a measuring function (Im)

RISK CLASS

CONDITIONS FOR MDD CERTIFICATES THAT EXPIRED **BEFORE** 03/20/2023

- before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII of MDR for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;
- a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.

CONDITIONS IN THE CASE OF MDD CERTIFICATES EXPIRING **AFTER** 03/20/2023

- those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- there are no significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10 (9) of MDR;
- no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device or in respect of a device intended to substitute that device, and,
- no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

QTICS medical

MDR DEADLINES BASED ON RISK FACTORS

SPECIAL RULES

According to MDD, it can be placed on the market or put into service

26. 05. 2026.

- **class III custom-made implantable devices**

DEVICE GROUP

CONDITIONS

- the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment, and, no later than 26 September 2024,
- the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

According to MDD, it can be placed on the market or put into service

31. 12. 2028.

- Devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to MDR requires the involvement of a notified body

DEVICE GROUP

CONDITIONS

- those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- there are no significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10 (9) of MDR;
- no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device or in respect of a device intended to substitute that device, and,
- no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

QTICS medical