

EC Declaration of Conformity

Manufacturer

<Company Name>

<Company Address>

Medical Device

<Name of Device>

<Version of Device>

<Basic UDI-DI, if applicable>

Classification

Medical Device Class: <enter class>

Classification based on <enter MDR reference, for example: Annex VIII, Chapter 3, Paragraph 6, Rule 13 (for class I active devices)>.

For context, read Chapter 5, Section 1, Art. 51 MDR. You can find the classification rule applicable to your medical device set out in Annexes VIII of the MDR.

For example: software intended to provide information used to take decisions with diagnosis or therapeutic purposes and software intended to monitor physiological processes is classified as class IIa according to rule 11 of the Annex.

Conformity Assessment

Conformity assessment procedure: <enter reference to applicable Annex, for example for class I: Annex I and III> of the Regulation (EU) 2017/745.

For context, read Chapter 5, Section 2, Art. 52 MDR. You can find the conformity assessment procedures applicable to your medical device class set out in Annexes IX to XI of the MDR:

- For class III devices (other than custom-made or investigational devices) -> Annex IX. Alternatively: Annex X + XI
- For class IIb devices (other than custom-made or investigational devices) -> Chapters I and III of Annex IX, incl. TechDoc assessment according to Para. 4 of Annex IX for at least one representative device of a generic device group. For class IIb implant devices, Annex IX applies for every device. Alternatively, manufacturers may choose type examination following Annex X in combination with Annex XI.

- For class IIa devices (other than custom-made or investigational devices) -> Chapters I and III of Annex IX, incl. TechDoc assessment according to Para. 4 of Annex IX for at least one representative device for each category of devices.
- For class I devices (other than custom-made or investigational devices) -> draw up technical documentation according to Annexes I and III.
- For class I devices in sterile condition, including a measuring function or constituting reusable surgical instruments -> apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI.

The Medical Device referenced above meets the provisions of Regulation (EU) 2017/45 on medical devices.

Note #1: This document needs to be signed in some way. If you're using software which supports electronic signatures, use it to sign this document. Otherwise, print it out, sign it old-school, scan it and upload it to your QMS folder.

Note #2: read Annex IV MDR to double-check if all relevant information is included! For example, if applicable, include product / trade name, Notified Body information, etc.

Place, Date, Signature of CEO

Place, Date, Signature of PRRC

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