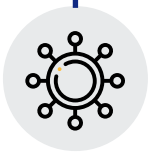
THE TECHNICAL DOCUMENTATION REQUIRED IN THE CONFORMITY ASSESSMENT OF MEDICAL DEVICES ACCORDING TO REGULATION (MDR) 2017/745

TÜV NORD

DOCUMENTATION



Quality Management System documentation

EN ISO 13485:2016
Medical devices — Quality management systems — Requirements for regulatory purposes

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The medical device technical documentation

Annex II MDR 2017/745
TECHNICAL DOCUMENTATION

Annex III MDR 2017/745
TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

As part of the preparation for the certification of a medical device in accordance with the requirements of Regulation 2017/745, it is necessary to prepare appropriate technical documentation.

The basic assumption is to provide:

- **compliance**
- **safety**
- documented **effectiveness**

of medical device

MDR 2017/745 ART.10 - GENERAL OBLIGATIONS OF MANUFACTURERS

Point 4.

Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

Point 8.

Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

DOCUMENTATION – GENERAL RULES

The technical documentation prepared by the manufacturer, shall be:

- presented in a clear way,
- well organised,
- readily searchable,
- unambiguous,
- and shall include all required the elements.

TECHNICAL DOCUMENTATION

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

2 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

3 DESIGN AND MANUFACTURING INFORMATION

4 GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

5 BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

6 PRODUCT VERIFICATION AND VALIDATION

DOCUMENTATION OF QUALITY MANAGEMENT SYSTEM

Based on MDR 2017/745, ART.10, Point 9.

- Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements Regulation (MDR) 2017/745
- Changes in device design or characteristics and changes in the harmonised standards or common specifications by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner.
- **Manufacturers of devices**, other than investigational devices, shall establish, **document, implement, maintain, keep up to date and continually improve a quality management system** that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.
- **The quality management system** shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of the Regulation 2017/745.

More information on the requirements of the quality management system can be found in the EN ISO 13485:2016 standard „Medical devices - Quality management systems - Medical devices - Quality management systems — Requirements for regulatory purposes"

EU DECLARACTION OF CONFORMITY

EU declaration of conformity according to Art. 19 and Annex IV for the product model covered by a given conformity assessment procedurę.

1. Name or business name, registered trade name or registered trade mark of the manufacturer and, where applicable, his authorized representative and, if already issued, their unique registration number as provided for in Article 31, together with the address of the registered place of business, at which they can be contacted and determine their location;

2. Statement according to which the EU declaration of conformity has been issued under the sole responsibility of the manufacturer;

3. Basic UDI-DI code referred to in Part C of Annex VI;

EU DECLARACTION OF CONFORMITY

4. Product name and trade name, product code, catalog number or other unambiguous reference enabling the identification and traceability of the product to which the EU declaration of conformity applies, such as a photograph, where applicable, and its intended use. In addition to the product name or trade name, identification and traceability information can be provided using the Basic UDI-DI code.
5. The risk class of the medical device in accordance with the rules set out in Annex VIII;
6. A statement that the product to which the declaration relates complies with this Regulation and, where applicable, with any other relevant EU legislation that provides for the issuing of the EU declaration of conformity;
7. Indication of any common specifications used and with which compliance is declared;
8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure carried out and identification of the issued certificate or certificates;
9. Where appropriate, additional information;
10. Place and date of issue of the declaration, name and surname and position of the person who signed the document, and an indication of the authorization of the person who signed the document, signature.

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

ANNEX III MDR 2017/745
TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

Prepared by the manufacturer pursuant to Art. 83-86, the technical file for post-market surveillance shall be drawn up in a clear, structured, easily searchable and unambiguous manner, and shall contain, in particular, the elements described in Annex III.

The post-market surveillance plan drawn up pursuant to Art. 84

The post-marketing surveillance report referred to in Art. 85

Medical device class I
– if necessary, it is updated / periodic documentation review

Periodic safety update report referred to in Art. 86

Medical device class IIa
– not less frequently than every 2 years

Medical device class IIb, III
– not less frequently than once a year

THANK YOU