

EU 2017/745 DOCUMENTATION SUBMISSION

Signatures

Signatures are required for any signed document in the file. Signatures can be handled in several ways:

- Documents may be digitally signed.
- Signature pages can be scanned in and inserted into the electronic document.
- All protocols/reports which require approval except for the Declaration of Conformity, must have undergone requisite approvals and be submitted with evidence of approvals.

Submission Method

- Technical documentation shall be transmitted to NOTICE via private, time-limited and encrypted links.
- No hard copies of Technical Documentation.

**Submission and Technical Documentation Contents**

- Cover letter
- The Technical Documentation itself

Electronic File Format

- Documents should be provided as paginated, fully searchable bookmarked PDF files
- PDF files and attachments should not be file protected or locked.
- File names should be logical and reflect the information covered within that part.
- Documents should be bookmarked.
- Manufacturers scanning directly from printed pages should utilise Optical Character Recognition (OCR).

Document Language

All submitted Technical Documentation and test results must be in English.

1. Submission and Technical Documentation Contents 

Two things are required for any Technical Documentation review:

- Cover letter (i.e., an explanation of what is being requested and why)
- The Technical Documentation itself

1.1. Cover letter 

The cover letter should contain an executive summary containing at least the following details:

- Certificate # reference(s) (if known)
- The type of review (new product, design change, shelf-life extension, etc.)
- Brief product description, including model numbers involved, etc.
- An explanation of:
 - ▲ what has been submitted and how it demonstrates compliance and, for changes to existing certification:
 - ▲ what is affected (packaging, material change, sterilisation, etc.)
 - ▲ what is not affected (along with appropriate justification)

1.2. Technical Documentation

Content of TD is explained in section 6.

2. Submission Method



- Technical documentation shall be transmitted to NOTICE via private, time-limited and encrypted links
- We do not accept hard copies of Technical Documentation.

3. Document Language



The official language of NOTICE is English, and all submitted Technical Documentation and test results must be in the English language.

4. Electronic File Format



- Documents should be provided as paginated, fully searchable bookmarked PDF files
- PDF files and attachments should not be file protected or locked as this prevents necessary access and file manipulation for archiving.
- File names should be logical and reflect the information covered within that part
- Documents should be bookmarked to ensure ease of navigation
- Manufacturers scanning directly from printed pages should utilise Optical Character Recognition (OCR) so that as much of the resultant PDF file is searchable as possible.

5. Signatures



Signatures are required for any signed document in the file. Signatures can be handled in several ways:

- Documents may be digitally signed.
- Signature pages can be scanned in and inserted into the electronic document.
- All protocols/reports which require approval (as per the legislative requirements & Manufacturer's own procedures and policies), except for the Declaration of Conformity, must have undergone those requisite approvals and be submitted with evidence of those approvals (typically through dated and signed reports, signed protocols, or evidence of approval in an electronic system etc)

6. Content of TD



The submitted documentation shall include at least the following sections with all relevant content.

1. Cover Page for TD and Relevant Subparts/Documents:

- A cover page that outlines and references the corresponding sections within the TD.
- If applicable, a cover page for each subpart of the TD that maps and references the relevant information within the corresponding sections.

2. Manufacturer Identification Information:

- Manufacturer's name and contact details.
- Information on any trademarks owned by the manufacturer for the device.
- Address(es) of the manufacturer, including any branch locations.
- Brief company history.
- Details and contact information of the company representative.
- Details and contact information of the Person Responsible for Regulatory Compliance (PRRC) within the manufacturer's organization.
- For manufacturers with a registered place of business outside the EU: identification of the Authorized Representative within the EU, along with copies of the mandate and related agreements.

3. Device Description and Specifications:

- Product name or trade name, accompanied by a general description of the device.
- Basic UDI-DI assigned by the manufacturer in accordance with Annex VI, Part C of EU Regulation 2017/745 (MDR).
- Intended patient population.
- Medical conditions to be diagnosed, treated, and/or monitored, including relevant factors such as patient selection criteria, indications, contraindications, and warnings.
- Principles of operation of the device.
- Mode of action of the device.
- Justification demonstrating that the product meets the definition of a medical device as per Article 2(1) of EU Regulation 2017/745 (MDR).
- Device risk class and justification for the classification rule applied, in accordance with Annex VIII of the MDR.
- For novel devices, an explanation of the novel features.
- For devices intended to be used with accessories, a description of such accessories.
- For devices intended to be used in combination with other devices, a description of compatible devices.
- Description or complete list of configurations, variants, or models of the device intended to be made available on the EU market.
- If applicable, a general description of key functional elements (e.g., parts, components, or software), and the general formulation, qualitative and quantitative composition of the device. Where relevant, pictorial materials (e.g., diagrams, photographs, or drawings) shall be included.
- Description of raw materials intended to come into direct or indirect contact with the human body.
- Description of the technical specifications of the device and its accessories (e.g., features, dimensions, and performance claims for all variants/configurations/models). If available, marketing materials intended for the user shall be provided.
- If applicable, an overview of or reference to previous and/or similar generations of the device.

- In case of orphan devices,
 - justification for being orphan device.
 - description of orphan population/subpopulation.
 - device description.
 - justification for having insufficient alternatives to device.
 - Expected clinical benefits
 - Orphan indications
- In the case of systems or procedure packs, a justification demonstrating that the product qualifies as a system or procedure pack in accordance with the relevant provisions of EU Regulation 2017/745 (MDR).

4. Information Material Supplied by the Manufacturer:

- A complete set of labels, designed in accordance with Annex I, Section 23 of EU Regulation 2017/745 (MDR), applied to the device and all levels of packaging (e.g., single-unit, sales, and transport packaging), provided in the languages accepted in the Member States where the device is intended to be placed on the market.
- Instructions for Use (IFU), designed in accordance with Annex I, Section 23 of EU Regulation 2017/745 (MDR), provided in the languages accepted in the Member States where the device is intended to be placed on the market.
- For implantable devices, an implant card in accordance with Article 18 of EU Regulation 2017/745 (MDR).
- For devices operating with external or internal apps,
 - Contact information according to Article 3(13) of Regulation (EU) 2019/1020 and other EU laws.
 - Clear and unambiguous information of products or services promoted or offered to consumers located in the EU through the services of the providers, including MDSW.
 - Any sign identifying the trader such as the trademark, symbol or logo.
 - Where applicable, the information concerning the labelling and marking in compliance with rules of applicable EU law on product safety and product compliance.
- In case of electronic informational materials, evidence showing compliance to EU 2021/2226 regulation.

5. Design and Manufacturing Information:

- Information sufficient to describe and understand the design and development stages of the device.
- Complete information and specifications for all manufacturing processes, including process validations and procedures for continuous monitoring and control.

- Complete information on final device testing and release criteria.
- Identification of all sites involved in the design and/or manufacturing processes, including suppliers and subcontractors.
- In cases where any part of the manufacturing process is subcontracted, a written agreement to ensure and guarantee the quality of the subcontracted services.

6. General Safety and Performance Requirements:

- Description or list of applicable general safety and performance requirements (GSPR) outlined in Annex I of EU 2017/745 MDR.
- Method(s) or solutions adopted to demonstrate conformity to each applicable GSPR.
- Reference to relevant harmonized standards, common specifications for each applicable GSPR.
- Reference to controlled documents (documents within TD or QMS records) providing evidence for compliance to each GSPR.
- A list for applied standards and guidance documents to any phase of life cycle of the device.

7. Benefit-Risk Analysis and Risk Management:

- A benefit-risk analysis performed according to Section 1 and 8 of EU 2017/745 MDR Annex I.
- Results of risk management and solutions adopted according to results of risk management.

8. Product Verification and Validation:

- Results of critical analyses of all verification and validation activities conducted to demonstrate the conformity of the device with the requirements of EU Regulation 2017/745 (MDR).
- Where other EU legislation is applicable, evidence demonstrating compliance with the relevant legislative requirements.
- Results of preclinical testing, such as engineering tests, laboratory tests, simulated use tests, and animal studies.
- Evaluation of published literature relevant to the device or similar devices concerning preclinical safety and conformity with applicable specifications.
- Detailed information on preclinical tests, including test design, test protocols, test results, data analysis methods, and conclusions. Where applicable, this information shall include evidence demonstrating conformity with Directive 2004/10/EC on Good Laboratory Practice (GLP) and verification of its application to tests involving chemical substances.
 - Biocompatibility of the device including the identification of all materials directly or indirectly contacting with patient or user.
 - Physical, chemical and microbiological characterisation.
 - Electrical safety and electromagnetic compatibility.
 - Results for software verification and validation studies (describing the software design and development process and evidence of the validation). This information shall also

- include provided hardware configurations, operating systems in the informational materials.
- Stability tests, including shelf life.
 - Performance and safety tests.
 - If applicable, magnetic resonance imaging safety for implants.
- If any required tests have not been conducted, a justification for their omission
 - All external testing shall be conducted by accredited laboratories (EN ISO 17025 or GLP).
 - The Clinical Evaluation Report (CER), its updates, and the Clinical Evaluation Plan (CEP), prepared in accordance with Article 61 of EU Regulation 2017/745 (MDR).
 - Where applicable, a Summary of Safety and Clinical Performance (SSCP) in accordance with Article 32 of EU Regulation 2017/745 (MDR).
 - The Post-Market Clinical Follow-up (PMCF) Plan and PMCF Evaluation Report in accordance with Annex XIV, Part B of the MDR, or a justified rationale for the inapplicability of PMCF.
 - For devices incorporating, as an integral part, a substance referred to in point 2 of Article 1 of Directive 2001/83/EC (including medicinal substances derived from human blood or plasma), a declaration of such substances shall be provided.
 - For devices incorporating, as an integral part, a substance, identification of the source of the substance and test results demonstrating its safety, quality, and usefulness in relation to the intended purpose of the device shall be included.
 - For devices composed of absorbable substances or combinations of substances, detailed information on test design, test protocols, test results, data analysis methods, and conclusions regarding the following aspects shall be provided. Where such studies are not available, a scientifically justified rationale shall be included.
 - Absorption, distribution, metabolism and excretion characteristics of substances in human body.
 - Possible interactions of substances (including side-products released as results of metabolism of those substances) with other devices, medicinal products or other substances considering the target population, and their medical conditions.
 - Local tolerance
 - Toxicity (including single-dose toxicity, repeated-dose toxicity, genotoxicity, carcinogenicity, reproductive and developmental toxicity), as applicable depending on the level and nature of exposure to the device.
 - In case of devices containing CMR or endocrine-disrupting substances referred to in section 10.4.1 of EU 2017/745 MDR Annex I, justification referred in Section 10.4.2 of same Annex.
 - In case of not including any medicinal substances, human blood/plasma, animal tissue, a declaration in this regard according to relevant EU legislations.
 - In case of sterile devices or devices with defined microbiological conditions,
 - A description of environmental conditions for manufacturing process.

- For sterile devices, sterilization method and validation studies for the relevant method, along with sterile barrier verification and validation studies. The sterilization validation shall address bioburden testing, pyrogen testing and sterilization agent residues (where it is applicable).
- In case of devices with measuring function, a description of the method used to ensure accuracy of measurement done by the device.
- In case of reusable devices,
 - Evidence for conformity of cleaning, re-sterilization, disinfection, maintenance activities including relevant verification and validation studies.
 - Reusability limits
- In case of system or procedure packs, a declaration and evidence for performing the sterilization according to information materials available for the products in the system/procedure pack.
- In case of devices intended to be connected to other devices in order to operate as intended, a description of such combination/ configuration along with evidence for compatibility of these combinations/configurations. In such cases, all possible combinations/configurations shall comply with relevant GSPR, and relevant evidence shall be provided in TD.
- Usability evaluation study, including protocols, reports and relevant evidence, demonstrating safe use of the device.

9. Declaration of Conformity:

- A declaration of conformity prepared according to Annex IV of EU 2017/745 MDR shall be provided within TD.

10. Post Market Surveillance Documents:

- If applicable, post market surveillance plan prepared according to Article 84 of EU 2017/745.
- If applicable, post market surveillance report prepared according to Article 85 of EU 2017/745.
- If applicable, periodic safety update report prepared according to Article 86 of EU 2017/745.
- If applicable, post market clinical follow up plan prepared according to Article 61(11) of EU 2017/745.
- If applicable, post market clinical follow up report prepared according to Article 61(11) of EU 2017/745.

Contact Information

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