Disclaimer

This is a template and must be adapted according to the requirements of the manufacturer/product. This also applies to the corporate design as well as any requirements of the manufacturer's quality management.

All contents of this template are based on the current interpretations of the regulatory requirements.

The pre-entered contents must always be critically reviewed, adapted or supplemented in relation to the product. THIS IS NOT A FILL-IN TEMPLATE ONLY.

Further notes on the application of the template

Yellow markings are to be checked and supplemented or adapted

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Logo manufacturer	**Technical Documentation**	Revision: x.x
Product(s) or trade name(s) / *product group/family*		

Releases:

	Name	Date / Signature
Author:	xxx	YYYY-MM-DD
Reviewed by:	xxx	YYYY-MM-DD
Released by:	xxx	YYYY-MM-DD

Document history:

Revision	Date	Changes	Author
1.0	YYYY-MM-DD	Initial version	xxx

Content

The table of contents and all automated captions and references in the document must be updated after finalizing the content.

Logo manufacturer	**Technical Documentation**	Revision: x.x
Product(s) or trade name(s) / *product group/family*		

Introduction

Annex II - Regulation (EU) 2017/745

1 Device description and specification, including variants and accessories

1.1 Device description and specification

a) product or trade name and a general description of the device including its intended purpose and intended users

Product/ trade name	UMDNS code	GMDN code	*EMDN code*
xxx	**xxxxx** Description: …	**xxxxx** Description: …	***xxxxx*** *Description:* …

Also explain brief general description of the product.

Intended purpose

Refers to the use for which a product is intended according to the manufacturer's labeling, instructions for use, or promotional or sales material, or advertising or sales claims, and its statements in the clinical evaluation.

The actual medical purpose, i.e., what disease or injury is to be diagnosed, treated or monitored. In other words, it is what is to be achieved by the product.

Intended users

The intended user of the medical device is the person who uses the device. He may or may not derive any benefit from the product, i.e. user and patient may or may not be the same.

Are there any requirements for the user's qualifications? Is special training or instruction in the use of the product necessary?

b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability

Basic UDI-DI: xxx

Brief description of the composition of the basic UDI-DI (e.g. company identification, model identifier/product reference, check character) and information on the issuing authority (GS1, HIBC, etc.).

Assistance can be given e.g.

- *MDCG 2022-7: Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)*
- *MDCG 2021-19: Guidance note integration of the UDI within an organisation's quality management system*
- *MDCG 2018-1: Guidance on basic UDI-DI and changes to UDI-DI*

c) the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indica-

1-4	Non-invasive devices		

	Applicable (A) /	Justification acc. to

j) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and,

b) an overview of identified similar devices available on the Union or international markets, where such devices exist

A selection of similar products from the competition / competitor products, incl. supporting documents (e.g. instructions for use, brochures, excerpts from websites, etc.)

2 Information to be supplied by the manufacturer

c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed

The design and manufacture takes place in the following places:

Company	Address	Activity description
		–
		–
		–

Where does/did the development take place, where do which production processes take place? Including details of any outsourced (sub)processes. In the case of outsourced processes, details and evidence of agreements (e.g. quality assurance agreement) should be given.

4 General safety and performance requirements

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply

b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement

c) the harmonised standards, CS or other solutions applied

d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation

The verification of compliance with the essential safety and performance requirements in accordance with Regulation (EU) 2017/745 is maintained in a checklist. The applicable standards and verification documents are referenced in detail in this list. If a requirement is not applicable, a corresponding justification is provided.

Specification and provision of the following verification documents:

- *GSPR list (General safety and performance requirements) according to point **Fehler! Verweisquelle konnte nicht gefunden werden.** 0, 0, 0, 0*
- *List of applicable regulations (laws, directives, regulations, standards, MDCG guidelines, etc.) according to point **Fehler! Verweisquelle konnte nicht gefunden werden.** 0*
  For assistance, see e.g. MDCG 2021-5 Guidance on standardisation for medical devices.

- *Content overview of all verification documents of the technical documentation incl. revision status/date acc. to point* ***Fehler! Verweisquelle konnte nicht gefunden werden.*** *0*

5 Benefit-risk analysis and risk management

a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I

- *software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and*

[1] Richtlinie 2004/10/EG des Europäischen Parlaments und des Rates vom 11. Februar 2004 zur Angleichung der Rechts- und Verwaltungsvorschriften für die Anwendung der Grundsätze der Guten Laborpraxis und zur Kontrolle ihrer Anwendung bei Versuchen mit chemischen Stoffen (ABl. L 50 vom 20.2.2004, S. 44).

d) the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable

Post Market Clinical Follow-up (PMCF) is part of Post Market Surveillance (PMS). PMCF activities fill gaps that cannot be answered during clinical evaluation, such as long-term behavior of the medical device, monitoring of possible side effects and contraindications.

According to Annex XIV Part B of Regulation (EU) 2017/745, the PMCF plan describes all methods and procedures for proactively collecting and evaluating clinical data. The evaluation of clinical

- *absorption, distribution, metabolism and excretion;*
- *possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;*
- *local tolerance; and*
- *toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.*

In the absence of such studies, a justification shall be provided.

d) In the case of devices containing CMR or endocrine-disrupting substances referred to in Sect.

Annex III - Regulation (EU) 2017/745

The TD shall contain the post-market surveillance (PMS) documentation to be prepared by the