Guidance for MDR
Technical Documentation Submissions

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1 Introduction

Manufacturers shall ensure the conformity of medical devices being placed on the European market in accordance with the applicable requirements of (EU) 2017/745 Medical Devices Regulation (MDR). Depending on the classification of the device and the conformity assessment route chosen, a full Technical Documentation need to be assessed by a Notified Body. This Technical Documentation submission guidance is aligned to the requirements of (EU) 2017/745 Medical Devices Regulation (MDR), described in detail in Annexes II and III.

Tips to get started and Common Feedback

TÜV Rheinland and medical device manufacturers are keen to streamline and speed up the review of the Technical Documentation (as part of initial applications, substantial change notifications, renewal applications etc.) and reducing time to certification. The most common reasons for delays in Technical Documentation reviews are:

- Incomplete Technical Documentation - not all the information needed for the review were submitted by the manufacturer from the beginning.
- Unsuitable Technical Documentation Structure - the documentation and information is presented in a manner that it is difficult for TÜV Rheinland to verify compliance of the product in question to the regulation, especially with the **G**eneral **S**afety and **P**erformance **R**equirements (GSPRs) of Annex I
- Inaccurate references in the Technical Documentation - References are made to general TD sections (such as “Preclinical Data” or “Labelling”) and not precisely to the applicable source of information.

TÜV Rheinland has prepared this document in order to help facilitate and streamline the Technical Documentation submission and review process which in the end should allow the Notified Body TÜV Rheinland LGA Products GmbH (TRLP) to issue related certificate(s) under the Medical Devices Regulation (EU) 2017/745 (MDR). For the successful processing of MDR applications, one of the critical factors in the process is the quality and structure of Technical Documentations submitted for review. TÜV Rheinland recommends to take time and consider this guidance when creating Technical Documentation(s).

Please note: this document does not add or change any requirements defined in the MDR, but outlines exemplarily the information and documentation expected to be within the Technical Documentation. It is meant as a guidance, to check the Technical Documentation for completeness before submitting it to the Notified Body. However, TÜV Rheinland may request further documents and information beyond this list in line with the requirements of MDR in the course of the Technical Documentation review.

2 Submission

To begin…

1) Notify your contact person at TÜV Rheinland, that you have a Technical Documentation submission ready for review
2) You will receive a quotation if the TD review is not yet covered by an existing order.
3) Ensure you have the following ready before moving to the next step:

   - The current Product List and Application [PL&A] (MDR Annex IX/Annex XI, part A ("QMS part") and where applicable an application for MDR Annex IX, Chapter II, Section 4)
   - A cover letter accompanying the Technical Documentation submission containing the following information:
     - Certificate # reference(s) (if known)
     - 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)
   - The TÜV Rheinland (Significant) Change Notification (if applicable): TÜV Rheinland | TÜV Rheinland (TÜV.com)
   - The signed approved purchase order.
   - The submitted Technical Documentation itself (approved – do not submit drafts!) need to contain objective evidence to demonstrate compliance to the MDR (Annex I (GSPR), Annex II (TD) and Annex III (TD on PMS)).

     Whenever possible and practical, please provide a product sample of a product in its final packaging together with the Technical Documentation.

4) Technical Documentation review can begin upon receipt of a signed purchase order together with all the required application documentation (per Annex IX for initial submissions).

3 Preparing Technical Documentation

MDR is a new legislation, and for initial certification a complete submission with all relevant parts of the Technical Documentation included is required, no matter whether the device was previously certified under the MDD, or AIMDD or not.

For specific products, the MDR requires a TD review before initial certification. For other types of devices, a review of TDs per device group before certification is required, together with later additional reviews of other devices from the same group based on a sampling approach over the period of certificate validity. The Technical Documentations to be reviewed for initial certification will be determined by TRLP based on the application documents provided, in line with the requirements and guidelines of the MDR.

Note: For manufacturers with a high number of products, it is recommended to establish a transfer plan to successively transfer the products from MDD/AIMDD to MDR.

Furthermore it is crucial that only products which are evidently in compliance with MDR are listed on the application form. Otherwise it causes delays in the review and certification activities.

Particular attention needs to be given to devices that are also machinery, where the Machinery Directive 2006/42/EC is applicable in addition. Relevant requirements of that Directive will also need to be covered given their specificity (refer to Article 1(12)).

The Technical Documentation need to be accompanied by a Declaration of Conformity. For products already in the market under a MDR certificate, a signed Declaration of Conformity (e.g. for Technical Documentation based on a sampling approach) is expected. For new products, a draft of the Declaration of Conformity for the product needs to be part of the application.

The Technical Documentation has to contain consistent information throughout all sections, appendices, and attachments.

In case the product in question was not evidently tested itself, applicability of test reports has to be demonstrated for the device in question.

3.1 Language

In the pre-application phase (i.e. before TÜV Rheinland issues a quotation for the Technical Documentation assessment), we will ask you to provide information regarding the language of the Technical Documentation. It must be an official language of the European Union. We will confirm with you at that stage whether it is feasible for us to perform the assessment in the language in which you would like to

submit your Technical Documentation. We strongly recommend that you create the Technical Documentation in the English language.

Original test reports submitted as part of the Technical Documentation need to be translated accordingly. Documents not submitted in the required language are considered not to be part of the submission and must be excluded from the Technical Documentation and subsequently from any review activities.

3.2 Electronic File Format

3.2.1 Submission route

TÜV Rheinland can provide access to secure data transfer tools for the submission of your Technical Documentation.
We recommend you prepare ZIP files for the document upload (or you may split your set of documents in more than one file) while keeping your binder and file structure within the ZIP file(s).
Your TÜV Rheinland office serving you for our Technical Documentation assessment will provide further details on the electronic file submission process.

3.2.2 Format

Annex II of the MDR states “The Technical Documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.” Thus,

- Documents shall be provided as paginated, fully searchable, OCR (**O**ptical **C**haracter **R**ecognition) applied and bookmarked PDF files.
  Main sections as indicated in MDR Annex II “Technical Documentation” should be bookmarked, as well as any supporting attachments referenced to within the main body (i.e. executive summaries) of the Technical Documentation.
- Clear folder organization and easy navigation will make it easier to find documents and may therefore reduce overall time required for the review.
- An index or detailed table of contents has to be part of the Technical Documentation.
- File names should be self-explanatory, reflecting the information included within the documents. File names should be appropriately cross-referenced in the TD Overview, see the Annex in this document.

- For each main section specified in the MDR Annex II, one PDF file should be submitted. Each section shall contain an executive summary including the references to the accompanying documents, which contain the documented evidence (e.g. reports). These documents have to be either embedded or filed as separate PDFs along with the section.

- Approvals/signatures are required for any submitted document in the file (signed and dated). No draft versions (except for the Declaration of Conformity and SSCP being part of initial certification submissions) shall be part of the TD submission.

3.2.3 Review process

The Technical Documentation assessments are performed by assigned reviewer(s) on behalf of the Notified Body TÜV Rheinland LGA Products GmbH.

After the date of submission is agreed between manufacturer and TRLP, the manufacturer needs to provide the submission according to section 3.2.1 Submission route to TÜV Rheinland on this agreed date.

Incomplete TD submissions from manufacturers are one of the most common reasons for questions being raised by our Notified Body reviewers and ultimately can lead to delays in the assessment of TD and the certification process. To make the process more efficient for you and to ensure that we receive a full and thorough submission, we are performing a completeness check. The completeness check is the first step of the TD assessment process before we progress and commence a full in-depth review of the TD. During the review process questions from the reviewers may arise which need to be addressed by additional information to be provided by the manufacturer. In order to maintain an efficient project management, we would like to ask for your understanding that overall project time-lines have to be defined and kept. Therefore, TÜV Rheinland reserves the right to cancel the project and/or decide on further measures if review items still remain open after three rounds.

The completeness check does NOT count as one of the three rounds of questions. However, failure to provide a full set of TD after two attempts may lead to refusal of the application for the subject device(s) or to rescheduling of the review.

For clarification on questions during the TD review, please provide answers to the corresponding questions within 20 business days after receipt of the questions documented in the “Technical Documentation Assessment MDR - Questions and Answers List”. In cases, where TÜV Rheinland requires further or more detailed evidence of compliance to the MDR, the Technical Documentation must be updated accordingly. To support the review workflow, the revised Technical Documentation must be accompanied by a revision history indicating any change in comparison to

the initial submission. New or revised documents have to be highlighted as such. Also documents, which were declared obsolete have to be indicated. Obsolete or outdated documentation shall not be part of the submission for Technical Documentation review.
All answers provided by manufacturers should include a reference to the document number, document name, section and page number that was changed.

To reflect the changes made to the Technical Documentation, a redlined document of the “Annex A: Information on TD Deliverables” should be submitted together with the revised Technical Documentation.

Note: If it is not obvious which parts/documents were revised or updated, the re-review of the complete Technical Documentation will be required and will add review times and by that additional review costs.

TRLP has created the “Annex A: Information on TD Deliverables” included with this document, that contains examples of documentation expected in the different sections of the Technical Documentation. However, please refer to MDR Annex II and III for the respective requirements to be addressed.

3.2.4 Significant changes

For devices already reviewed and covered by a certificate, it is crucial to describe the reason for the change(s) including its intended effect(s).

The TÜV Rheinland Significant Change Notification (SCN) forms may be applicable in certain cases (e.g. new products, design changes, shelf life extensions, manufacturing changes etc, depending on the risk class of the products and their conformity assessment).

For submissions in the context of scope extensions or significant changes, as far as is practical, submissions should be stand-alone and not refer to previous submissions for evidence of compliance. A consolidated revised Technical Documentation is expected, highlighting the changes in the “Annex A: Information on TD Deliverables” and indicating new or revised, obsolete or replaced documents as opposed to the previous already reviewed Technical Documentation revision. Any changes or removals of critical suppliers/subcontractors require a revised Product List and Application, along with a Significant Change Notification, if applicable.

If you remove a critical supplier/subcontractor, please also provide justification for their removal.

Note: Before another SCN for a specific Technical Documentation is applied, the previous SCN review needs to be successfully closed and accepted by the certification department.

Annex A: Information on TD Deliverables

Please use this Annex as follows: Please add into the “Page/section or NA” column the detailed location of the document within the Technical Documentation. Into the column “Referenced evidence (Document Title & No., Applicable Chapter, Section etc.) or in case of N/A include justification” please add the respective information as applicable for the submitted Technical Documentation. You may use the “Check off”, when you have fully completed the respective section.

Ref to MDR	Requirement	Each column to be completed by customer		
		Page / section or N/A	Referenced evidence (Document Title & No., Applicable Chapter, Section etc.) Or in case of N/A include justification	Check off
Application (1)				
	“Product List and Application MDR (QM part)” (MS-0030360) **and/or** **“Product list and Application MDR, Technical Documentation assessment, Annex IX, chapter II” (MS-0030497)** **or** **“Product List and Application MDR, Product Verification” (MS-0030499)**		*The following information should be listed on the Product List and Application:* *Identification of the legal manufacturer, who is placing the device on the market. This should be consistent across the device labels, IFU and Declaration of Conformity. The Single Registration Number (SRN) of the legal manufacturer should be identified.* *The name and location of the EU Authorized Representative should be identified if required. Only one EU Representative should be identified, and this should be consistent across device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the EU Authorized Representative should be identified.* *The site(s) responsible for design need to be identified, either external and/or internal.* *All relevant sterilization facilities, internal/external manufacturing facilities, etc., must be listed on your Product List and Application.* *In the column “Product name (as listed on label)” the product names need to be listed as identified on the labels. Please complete all lines of the table with the requested information, where applicable.*	
	Cover page(s) and table of contents of the Technical Documentation		*As part of the application, provide the cover page of the Technical Documentation.* *Please provide the detailed Table of Contents for Technical Documentation.*	
	Technical Documentation revision history		*Please provide the revision history of the Technical Documentation, including reason for Technical Documentation revision*	

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	Presentation of Technical Documentation		*Please ensure that the Technical Documentation is provided in a clear, organized, readily electronically searchable and in unambiguous manner*	
Device description and specification (2)				
1.1. (a)	**General description, including intended purpose and intended users** **(MDN, MDA, MDS-codes (refer to MDCG 2019-14) as well as information whether device is for single use only, multiple use, reprocessing and its number of cycles)** **(including description of packaging)**		*The device description should enable understanding of the design, packaging, sterilization, or other characteristics of the device.* *Sufficient information should be provided to understand the intended purpose of different design features.* *The intended purpose or intended use should provide enough detail to explain the disease conditions the device is intended to treat or monitor.* *Intended use shall be consistent throughout the Technical Documentation (e.g. Instructions for Use, clinical evaluation documentation, etc.). The classification rule of Annex VIII need to match with the intended purpose of the device.* *Identify the intended users of the device (i.e. medical professionals in a specialty, clinical nurses, lay-persons, etc.). Intended users as claimed shall be substantiated by the clinical evaluation / usability file.* *Please provide device information on single use, multi-use, or reuse including its number of reprocessing cycles, if applicable.*	
1.1. (b)	**Clear identification of device by unambiguous reference allowing traceability** **Basic UDI-DI** *(Additional guidance on Basic UDI-DI may be found in the MDCG documents published on the EU Commission website.)* **EMDN code** *(European Medical Device Nomenclature (EMDN code) shall be identified, refer to guidance published on the EU Commission website)*		*Clear identification of device by unambiguous reference, allowing traceability (Basic UDI-DI), together with other traceable reference number (e.g. product code, catalog number, etc.)* *Information to be consistent also with the information on the labeling.* *Note: Basic UDI-DI need to be consistent with the information on the respective Product List and Application*	
1.1. (c)	**Intended patient population and medical condition to be diagnosed, treated and/or monitored (incl. e.g. patient selection criteria, indications, contra-indications, warnings)**		*Identify the Intended patient population and medical condition to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings* *The information needs to be consistent throughout the Technical Documentation, especially the clinical evaluation, risk management, labelling, etc.*	

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		Page / section or N/A	Referenced evidence (Document Title & No., Applicable Chapter, Section etc.) Or in case of N/A include justification	Check off
1.1. (d)	**Principles of operation of the device and its mode of action, scientifically demonstrated if necessary;**		*The basic principles of operation, including e.g. additional devices/accessories needed, intended users, environment.* *The information needs to be consistent throughout the Technical Documentation, especially clinical evaluation, risk management, labelling, etc.*	
1.1. (e), (f)	**Rationale for the qualification of the product as a device,** **justification for the risk class and classification rule (Annex VIII, Chapter III)**		*The intended use must include the use of the device as a "medical device" as defined by MDR Article 2, unless the device is a product without a medical purpose as listed in MDR Annex XVI.* *Please indicate the device classification and the rationale for the classification rule including the sub-rules according to Annex VIII. If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.* *The justification for the device classification should be sufficiently robust in particular in borderlines cases, or in combination products.*	
1.1. (g)	**Explanation of any novel features**		*A description of novel features of the device need to be provided as part of the device description/specification section.* *Please explain whether novel features are novel in comparison to other devices in the market and/or novel in comparison to other devices of the manufacturer.* *Novel features must be accompanied by scientific evidence, as e.g. from clinical investigations* *(Note: novel features might require a clinical investigation also in case of class IIa or IIb devices.)*	
1.1. (h)	**Description of all accessories/product intended to be used with the device**		*Please provide a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device.* *Evidence need to be provided demonstrating the compatibility of the devices with any applicable accessories/product within the Technical Documentation.* *If the accessories are part of the device and as such packaged with the device, please note that the applicable information and evidence of compliance to the MDR are needed for all products/accessories, i.e. the complete content of the packaging.*	
1.1. (i)	**Description of all configurations/variants of the product**		*All configurations/variants of the product covered by the Technical Documentation need to be clearly identified.* *Please provide sufficient information to distinguish different variants of the device.*	
1.1. (j)	**General description of key functional elements (parts/components, formulation, composition, functionality and, where relevant, qualitative and**		*General description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition.* *Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;* *Note: This is important for pre-clinical aspects, such as safety concepts, risk management aspects, testing of e.g.*	

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	quantitative composition)		*physical/mechanical/electrical properties etc., compatibility with other products/accessories, etc. as well as clinical aspects*	
1.1. (j)	**Mechanical drawings, photographs**		*Critical aspects of the specifications including tolerances should be included. This may consist of Critical to Quality aspects, critical dimensions, and a list of critical components/ingredients shall be provided.*	
1.1. (j)	**Electrical circuits (block diagram)**		*For active medical devices, electrical circuit diagrams shall be a part of the Technical Documentation and should enable the reviewer to understand the electrical safety concept and identification of all relevant electrical components.*	
1.1 (k)	**Raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body**		*Please identify the raw materials incorporated into key functional elements of the device including information on any coatings. The nature of contact with the human body (e.g. direct or indirect contact, contact with circulating body fluids etc.) should be clearly identified.* *Please add the Bill of Materials of the device.*	
1.1. (l)	**Technical specifications as typically claimed in e.g. catalogues, brochures (e.g. features, dimensions, performance attributes, etc.) of the device and the accessories**		*Product specifications including tolerances are to be defined for the devices as well as devices and/or accessories, which would typically be used with the device during the procedure (compatibility of the products)* *Specifications shall be consistent throughout the Technical Documentation, all labeling and clinical evaluation documentation.*	
Previous and similar generations of the device (3)				
1.2. (a)	**Previous generation produced by the manufacturer**		*Previous or similar generations of the product shall be described outlining the differences with the presented product generation.* *Information may be important to explain the relevance of data for e.g. the clinical evaluation, **p**ost-**m**arket **s**urveillance (PMS) and **p**ost-**m**arket **c**linical **f**ollow-up (PMCF).*	
1.2. (b)	**Similar devices available on the Union or International market**		*Please provide a list and brief description of any similar devices that are available on the Union or International markets. This may also be important in the interest of e.g. the clinical evaluation, PMS and PMCF.*	
Labeling (4) *In regard to language requirements, please refer to MDR, Article 10(11): "Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient."*				
2.1	**Complete set of Labels** (as on the device, on the (e.g. single unit) packaging, sales packaging, transport in case of specific conditions)		*Please provide the complete set of labels as used on the device itself, the sterile barrier, the protective/sales packaging, transport packaging etc.* *Please clearly identify the position of the respective label (e.g. by photographs) on the final device and all parts of the packaging respectively.*	

Ref to MDR	Requirement	Each column to be completed by customer		
		Page / section or N/A	Referenced evidence (Document Title & No., Applicable Chapter, Section etc.) Or in case of N/A include justification	Check off
	(see Annex I, #23.2 and #23.3)		*Please ensure that labels are one-to-one copies. Please ensure that the copy reflect the label as intended.* *If the device has a sterile barrier, clearly identify the label for the sterile package. If any of the packaging is printed with information for the user (including pictures / schematics of the device) this should also be provided.* *Please ensure that any specific requirements of relevant standards or CS are addressed on the labels.*	
2.2	**Instruction for use (IFU)** (see Annex I, #23.4)		*Please ensure that the information within the IFUs, especially related to the intended purpose, indications, contraindications, and other safety related information such as side effects, warnings are in line with the information within the Technical Documentation such as risk management, clinical evaluation, usability, pre-clinical performance data etc.* *Please ensure that any specific requirements of relevant standards or CS are addressed by the instructions for use. For example EN 60601-1, EN 60601-1-X, EN 60601-2-X, EN ISO 17664, EN ISO 14630 have specific requirements for the Instructions for Use.* *Please define the language requirements for the IFUs based on the target markets and provide the IFU including the respective translations.* *Some devices incorporate all the information relevant for the patient/user within the IFU itself. Some devices are accompanied by a separate patient handbook with instructions specific to the patient. Such parts of the labeling need to be provided as well, where applicable.* *If a separate physician's handbook is relevant for the device, this has to be provided as part of the Technical Documentation as well, where applicable.* *Please note, that any particular performance claims or product benefits stated in the IFU must be supported by adequate clinical data and/or design testing.* *Please provide the IFU in the final print-layout.*	
2.2	**Electronic Instructions for Use** (see Annex I, #23)		*If electronic Instructions for Use (eIFU) are provided for the device, the eIFU has to be in compliance with the requirements of Regulation 207/2012/EU (MDR, Annex I, #23.1. (f)).* *If applicable, please provide URL of the website where labelling information as relevant is included in Technical Documentation as per Annex I, #23.1*	
Article 18	**Implant card and information to be supplied to the patient with an implanted device**		*Please provide the Implant card and information to be supplied to the patient with an implanted device*	
Design and Manufacturing (5)				
3. **(a)**	**Information on design stages applied to the device**		*Please provide information on the design stages (stages like initial idea, risk analysis, conception, feasibility, design and development, verification and validation activities) applied to the device to be understood.*	

Ref to MDR	Requirement	Each column to be completed by customer		
		Page / section or N/A	Referenced evidence (Document Title & No., Applicable Chapter, Section etc.) Or in case of N/A include justification	Check off
			For devices already marketed, please include a history of any major changes to its design, including the reason for design changes. *For previously marketed devices certified under the MDD/AIMDD and applying for MDR certification, it is crucial to provide the following:* - *Any changes in the design of the device as approved under MDD /AIMDD vs. the application under MDR* - *a table of previously conducted testing identifying what testing is still relevant to the current version of the device* *Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision.*	
3. **(b)**	**Manufacturing processes, their validation, their adjuvants (including identification of the respective manufacturing line)**		*A general description of the manufacturing processes, including manufacturing technologies used and indication of special processes need to be part of the Technical Documentation.* *The detailed overview may be provided as manufacturing flowchart, including relevant information on e.g. location/site, class of clean room, inspection steps, critical process parameters, etc.* *Please identify the adjuvants used in the manufacturing processes, respectively.* *If certain critical manufacturing processes are outsourced, please provide a detailed overview of the manufacturing including relevant information on e.g. location/site, class of clean room, inspection steps, critical process parameters, etc.* *Please provide the Master Validation plan and validation reports of processes considered critical for the safety and performance of the device. Please consider this requirement also for critical processes being outsourced. Further information might be requested during the Technical Documentation review and/or during audits.*	
3. **(b)**	**Complete specifications (product specification, packaging specification, incoming inspection, continuous monitoring, in process controls, final product testing, installation specification)**		*Please provide the complete product specification of the finished device.* *Please ensure that the following information is provided within the Technical Documentation:* *Incoming inspection of e.g. critical raw materials, (sub-) components: Specifications / acceptance criteria* *Continuous monitoring / in-process controls and final product testing: Specifications / acceptance criteria* *Installation specification: Specifications and acceptance criteria, where applicable*	
3. **(c)**	**Site(s), including subcontractor(s), supplier(s) where design and manufacturing activities are performed**		*Please note, the site information, where design and manufacturing activities are performed, must align with the submitted Product List and Application.* *Internal and external manufacturing sites as well as all relevant subcontractors and critical suppliers/subcontractors need to be identified.* *Especially in cases where such certificates are not available, additional audits might need to be performed.*	

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			For critical suppliers/subcontractors, please include a justification for identifying the supplier as critical supplier. Please justify changes of subcontractors/suppliers, respectively.	
6.2 (e)	**In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps.**		*Environmental conditions for the relevant manufacturing steps need to be identified. (e.g. Class of cleanroom)* *Refer to applicable parts of the EN ISO 14644 series.* *Bioburden test results (methods/procedures) and evidence of bioburden testing need to be included for the products in question.* *(see e.g. Annex I, #11.6)*	
General Safety and Performance Requirements (6)				
4. (a)-(d)	**"General safety and performance requirements" document**		*Please provide a "General safety and performance requirements" document structured according to MDR, Annex II Section 4:* - *Containing a decision column on applicable versus not applicable for each clause/sub-clause of MDR, Annex I* - *Containing a decision column on each clause/sub-clause of MDR, Annex I that apply to the device and an explanation as to why others do not apply* - *Containing a column to add methods used to demonstrate conformity with each clause/sub-clause of MDR Annex I* - *Containing a column to add applied standards, **C**ommon **S**pecification CS or others for each clause/sub-clause of MDR respectively* - *Containing a column to add the precise identity of the controlled documents offering evidence of conformity with each applied standard, CS or other method applied and a cross-reference to the location of such evidence within the full Technical Documentation and, if applicable, the summary Technical Documentation for each clause/sub-clause of MDR, Annex I* *Please provide an overview of applicable standards/common specification/etc. and indicate, which of these were (fully or partially) applied, including version (state of the art).* *If outdated standards were applied, a gap assessment needs to be provided to demonstrate state of the art. If no new testing is deemed required, a justification needs to be provided.* *Refer to additional applicable standards, and/or directives – e.g. Machinery, EMC, RoHS, scientific opinions, guidance as necessary to show state of the art.*	
Benefit-Risk Analysis and Risk Management (7)				
5. (a)-(b)	**Risk Management:** **Risk management plan** (Refer to Annex. I, #3a)		*Please refer to the MDR requirements like Annex I, clauses 1-9.* *Please provide the relevant risk management file documents, especially the Risk Management Plan, Risk Management Report. The system used for qualitative or quantitative categorization of probability of occurrence of harm and severity of harm shall be recorded in the risk management file.*	

Ref to MDR	Requirement	Each column to be completed by customer		
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	Risk assessment including risk control (Refer to Annex. I, # 3b-e, #4) **Information from production phase and PMS on hazards and the frequency of occurrence thereof, risk acceptability including possibly adaption of control measures** (refer to Annex I, #3 f**)** **Overall residual risk evaluation including residual risk evaluation** (refer to Annex I, #8)		*Please clearly indicate whether the risk management process is based on EN ISO 14971.* *Please provide evidence that a safety concept in accordance with MDR, Annex I, clause 4 is applied.* *The risk management file needs clearly to reflect the interface between the risk management process and pre-clinical and clinical evaluations performed by the manufacturer (refer to Annex VII, 4.5.4(c) and 4.5.5.)*	
Annex I, 5	**Usability Evaluation** See e.g. Annex I, #14.6, #21.3, #22.1, #22.2, #23.1a		*Please refer to the MDR requirements like Annex I, clauses #14.6, #21.3, #22.1, #22.2, #23.1a* *Please refer to EN 62366-1.* *For ease of review, please also provide a use flow-chart for the device in question.*	
Pre-clinical (product validation/performance) data (8) *Note in general: In case testing is not performed on each product variant, the representative character of the tested product for a product range needs to be demonstrated considering the worst case approach.* *Furthermore test results must be provided in SI units.* *Determined sample sizes are to be justified for all testing, respectively.* *Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision.* *Please provide an executive summary, outlining the performed tests, test specification, test results incl. standard deviation, and conclusions drawn. The test reports themselves need to be attached to the executive summary report,*				
	Test laboratory accreditation (GLP/EN ISO 17025)		*In general, for the test laboratory/-ies used for testing of e.g. electrical safety, biocompatibility, bioburden, sterilization residuals, sterility tests etc. please provide the accreditation/designation of the respective laboratory.* *Please include the qualification of the test laboratories (e.g. accreditation including its attachment to accreditation) valid at the time of testing.*	
6.1. a	**Evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications**		*Please provide the evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications*	
6.1. (a-b)	**Chemical characterization**		*Please include the chemical characterization.*	
6.1. (a-b)	**Biocompatibility including identification**		*The biocompatibility evaluation report shall be written by an expert in this field and shall document the test strategy and shall*	

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	of all materials in direct or indirect contact with the patient and user Biological/ chemical tests/studies in animal models		*include a rationale for selection and/or waiving of biocompatibility tests and the use of any additional data to complete the evaluation. Include the overall biological safety conclusions for the medical device.* *In the case of test results are fail, a scientific based justification must be included why nevertheless sufficient biocompatible properties of the device is deemed to be demonstrated.* *Please ensure that the biological properties of the finished device in its final packaging is demonstrated by sufficient biocompatibility data considering the nature and duration of body contact.* *Data shall also demonstrate biocompatibility at the end of shelf life and over the life-time.* *The referenced biocompatibility test reports need to be attached to the biocompatibility evaluation report.* *Please demonstrate the qualification of the personal involved in the biocompatibility assessment (planning, execution, analysis).*	
6.1. (a-b)	**Performance and safety (physical/mechanical tests)**		*Include all necessary data to support t=0 and data supporting performance and safety of the device up to the end of the product lifetime (see also Annex I, #6).* *In case accelerated aging data are used, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25°C). Estimated dates by which the related real time aging data are available need to be provided, including interim time-points. Physical safety includes mechanical characteristics and safety related to conditions occurring under normal conditions of the intended use of the device, which may include e.g. ionizing and/or non-ionizing radiation.*	
6.1. (a-b)	**Electrical safety and electromagnetic compatibility**		*Provide all relevant evidence of compliance with the appropriate and current standards (applicable parts of the EN 60601 series)*	
6.1. (a-b)	**Software verification and validation including information on all of the different hardware confi-gurations and, where applicable, operating systems identified in the information supplied by the manufacture**		*Full lifecycle management must be demonstrated and provided as appropriate for the risk class of the software. EN ISO/IEC 62304 is the state-of-the-art approach.* *Note: Test report form may not be sufficient by itself.*	
6.1. (a-b)	**Simulated use testing/testing in animal models**		*Simulated use testing might have been performed as part of design verification, performance testing, design validation, usability testing or clinical studies. Please provide evidence of such type or any other type of simulated use testing here or refer to test reports provided as part of other sections of the TD.* *Simulated use testing may also be performed by testing in animal models.* *Simulated use testing and testing in animal models may also contribute to clinical evaluation.*	

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			Simulated use tests may also include simulation of product life time.	
Shelf life/ Transport simulation (9)				
6.1. (b)	**Product and packaging stability Tests, (up to the claimed shelf life)** See e.g. Annex I #7, #11.3, #11.4		*It needs to be demonstrated that the product incl. its packaging meets its specification after aging.* *Product stability data must be included up to and including the labeled shelf life.* *In case accelerated aging data are used initially, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25 °C).* *Estimated dates by which the related real time aging data will be available need to be provided, including interim time-points, where applicable.*	
6.1. (b)	**Transport evaluation/validation (product and packaging)** See e.g. Annex I #7, #11.3, #11.4		*Please provide the transport evaluation/validation for the product in its packaging.* *Please consider the respective environmental challenges of the product transport and justify the chosen test conditions (e.g. as required by transportation standards) accordingly.* *Transportation of the product to the end user must not have an impact on the quality, safety or performance of the device.* *The sterile barrier packaging validation related section can be found above, see Section 6.1(b) "Product and packaging stability tests".*	
Specific cases				
Devices incorporating a substance considered to be a medicinal product (10)				
6.2. (a)	**Medicinal substances(Annex IX, #5.2)**		*Ensure quality, safety and usefulness of the substance with methods specified in Directive 2001/83/EC, Annex I.* ***MDCG 2020-12:** Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues*	
	Source of medicinal substance (including manufacturer)		*Unequivocally identify the source of the medicinal substance*	
	Drug Master File (DMF) available for review		*Please indicate, which Competent authority is preferred to be consulted. Please indicate, which Competent authority has reviewed the DMF, if any.* *Please add a Letter of Access for the DMF from the DMF holder (manufacturer of the medicinal substance)* *Please provide the documents in the drug consultation documentation, which is required by the proposed competent authority.*	
	Test(s) conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.		*Please detail, where in the Technical Documentation and where in the drug consultation documentation the evidence on safety, quality and usefulness, taking account of the intended purpose of the device can be found*	
	usefulness of the substance as part of		*Please detail, where in the Technical Documentation and where in the drug consultation documentation the evidence on*	

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	the device taking account of the intended purpose of the device		*usefulness of the substance as part of the device taking account of the intended purpose of the device*	
Devices incorporating materials of animal origin (11)				
6.2. (b)	**Materials of animal origin**		*Please ensure that the requirements of MDR, Annex I, clause #13.1, # 13.2 and 13.3 are addressed in this part of the Technical Documentation.*	
	non-viable tissues or cells of animal origin, or their derivatives utilized in the manufacturing		*Please identify non-viable tissues or cells of animal origin, or their derivatives utilized in the manufacturing of the device*	
	animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues (Annex I, #13.2a)		*Please identify whether the animals were subject of appropriate veterinary controls*	
	Information about the geographical origin of the animals retained by the manufacturer (Annex I, #13.2a)		*Is the information about geographical origin of the animals retained by the manufacturer of the device?*	
	Sourcing, processing, preservation, testing and handling carried out so as to provide safety for patients, users and, where applicable, other persons (Annex I, #13.2b)		*Please provide evidence that the sourcing, processing, preservation, testing and handling is carried out so as to provide safety for patients, users and, where applicable, other persons.*	
	Safety with regard to viruses and other transmissible agents addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; (Annex I, #13.2b)		*Please provide evidence that the safety with regard to viruses and other transmissible agents is addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device.*	

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	Requirements on devices manufactured utilizing tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012		*Please detail whether the device is manufactured utilizing tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012.* *Please provide details on the material of animal origin and demonstrate compliance to Regulation (EU) No 722/2012.*	
Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body (12)				
6.2. (c)	**Materials intended to be absorbed by or locally dispersed in the human body** (Annex I, #12.2)		*Please refer to MDR, Annex I # 12.2 to address the specific aspects related to substances or combinations of substances that are absorbed by or locally dispersed in the human body*	
	absorption, distribution, metabolism and excretion tests		*For the evaluation of absorption, distribution, metabolism, excretion, please refer also to the requirements of Annex I to Directive 2001/83/EC*	
	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		*For the evaluation of local tolerance, please refer also to the requirements of Annex I to Directive 2001/83/EC*	
	local tolerance		*For the evaluation of local tolerance, please refer also to the requirements of Annex I to Directive 2001/83/EC*	
	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.		*For the evaluation, please refer also to the requirements of Annex I to Directive 2001/83/EC*	
	Justification in case above mentioned studies on absorbable or locally dispersed materials are not performed/provided		*Please add a scientific based justification in case related tests on absorbable or locally dispersed materials are not performed/provided*	
Devices containing CMR or endocrine-disrupting substances (13)				
6.2. (d)	**Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR)**		*Please refer to MDR, Annex I # 10.4.1 to address the specific aspects related to CMR and/or endocrine-disrupting substances*	

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	and/or endocrine disrupting substances			
	CMR concentration above 0,1 % weight by weight (w/w) where justified pursuant to Annex I, #10.4.2:		*Please refer to MDR, Annex I # 10.4.2 to address the specific aspects related to CMR and/or endocrine-disrupting substances* *In regard to labeling requirements please refer to MDR, Annex I # 10.4.5*	
Devices with a measuring function (14)				
6.2 (f)	**Devices with a measuring function including evidence of accuracy as specified**		*Please provide a description of the methods used in order to ensure the accuracy as given in the specifications* *Please refer to e.g. Annex I #14.2 (g), #14.6, #15*	
Combination, connection to other devices (15)				
6.2. (g)	**Accessories and detachable parts, other devices needed to operate as intended, including proof of safety and performance of the combination**		*Please provide a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacture.* *Please ensure that the labelling reflects the respective information.* *Please also refer to e.g. Annex I #14.1, #17.3, #23.4 (q), Annex II, 1.1 (h)*	
Sterile devices or devices in defined microbiological condition (16)				
6.1. (b)	Microbiological characterization: bioburden testing, pyrogen testing		*Information on the biological contamination of the device needs to be provided like:* *- Evidence of microbiological characterization, which is performed as part of the sterilization validation.* *- Bioburden and pyrogen test reports, including the information on the recovery rate.* *- Information on the respective alert and action limits.*	
6.2. (e)	Packaging validation (for sterile devices)		*If the device is placed in a primary/secondary package that is intended to be the sterile barrier, please provide the following:* *- Microbial barrier integrity of materials and seals for packaging* *- Packaging validation reports reflecting all seals* *- maintenance of sterility up to the labeled shelf-life (refer to EN ISO 11607-1)* *- Packaging system performance testing (handling, distribution, storage)* *In case accelerated aging data are used initially, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25°C).* *Estimated dates by which the related real time aging data will be available need to be provided, including interim time-points, where applicable.*	
	Description of sterilization method (including location)		*Please note, description and location must align with the information provided in the Product List and Application.* *Please provide copies of the EN ISO 13485 certificates including the relevant scope for the performed sterilization activities of the sterilization facility/ies.*	
	Validation of sterilization method		*Key characteristics of the sterilization process and the related initial validation and all relevant revalidations including all*	

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			attachments need to be provided (according to the respective sterilization standards). *Please ensure that the approach for the sterilization validation is clearly defined.* *In case the device in question was not part of the sterilization validation, the suitability of the sterilization validation for sterilization of the device needs to be demonstrated.* *Please provide the documentation according to the applicable standard for respective sterilization method.*	
	Testing for sterilant residues		*Test reports on the sterilization residuals need to be provided.* *The testing needs to be performed on device samples under consideration of a worst case approach.* *In case multiple sterilization cycles shall be allowed, the residual test results are to be provided according to the maximum number of sterilization cycle allowed.* *Refer to applicable standards like EN ISO 10993-7.*	
	Usage of preservatives		*In case preservatives are used, effects such as effects on biocompatibility of the finished device need to be evaluated. To be considered e.g. storage up to the labelled shelf-life.* *The potential impact on the patient and/or user and related risk / benefits of using preservatives needs to be evaluated.*	
	Reprocessing / sterilization before use		*In case reprocessing is claimed, the respective validation of the reprocessing process needs to be provided.* *The instructions provided in the IFU/user manual has to be substantiated by validation for cleaning / disinfection / sterilization / drying.* *Refer to EN ISO 17664. Please refer to e.g. Annex I, #11.2, #23.4m, #23.4n.*	
	Aseptic filling / sterilization filtration		*A description of the aseptic filling process has to be provided and the type of validation justified. Overall process validation is required, including the parameters and monitoring planned.* *Refer to EN ISO 13408-1 / EN ISO 13408-2.*	
Clinical data (17)				
6.1. (c)	**Clinical evaluation report and clinical evaluation plan** **Clinical investigation**		*For clinical evaluation, please refer to MDR, Annex XIV, Part A.* *Documents expected as part of the clinical documentation:* - *Clinical evaluation report (CER)* - *All attachments to CER (e.g. author CVs, Declaration of conflict of interest)* - *Clinical evaluation plan (CEP), including the attachments* - *Full text copies of the relevant published literature* - *Literature search protocol* - *Literature search reports* - *Full list of retrieved articles* - *Full list of excluded articles, with reasons for exclusion* - *Promotional material* *Please consider the guidance laid down in:* ***MDCG 2020-5** Guidance on clinical evaluation – Equivalence* ***MDCG 2020-6** Guidance on sufficient clinical evidence for legacy devices*	

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			Note: CER content will be reviewed and the review documented under application of the content required for the CEAR, ref. ***MDCG 2020-13*** *Clinical evaluation assessment report template* *Please justify the personal conducting and approving the clinical evaluation and demonstrate their qualification including their product and procedure related expertise.* *For clinical investigations, please refer to MDR, Annex XV.* *If clinical investigations (including post market clinical follow up studies) have been conducted:* - *Clinical investigation plan (CIP)* - *Clinical investigation report (CIR)* - *Ethics committee approval(s)* - *Competent Authority approval(s)* - *Competent/Regulatory Authority correspondence (from all countries, including outside of EU)* - *Proof of public registration of study* - *Publications in scientific journals (if applicable)*	
	Outcome of the Clinical evaluation consultation/ notification (class III implantable devices/class IIb active devices intended to administer and/or remove a medicinal product) (MDR Article 61, #2)		*Documentation related to the consultation of the expert panel with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation and the outcome of the consultation with the expert panel* *Reference, where in the clinical evaluation due consideration of the views expressed by the expert panel can be found*	
Article 32	**Summary of Safety and Clinical Performance (SSCP)** Note: SSCP for implant-table devices and class III		*Please follow the guidance laid down in* ***MDCG 2019-9****: Summary of safety and clinical performance*	
Post market surveillance (18)				
Article 84	**PMS plan**		*Refer to Annex III, #1.1*	
6.1. (d)	**Post-market clinical follow-up plan and evaluation report (update of clinical evaluation)**		*Please refer to MDR, Annex XIV , Part B* *Documents expected as part of the PMS/PMCF documentation:* - *PMCF plan (including CIP of planned PMCF studies)* - *PMCF report (where relevant)* *Please follow the guidance laid down in:* ***MDCG 2020-7*** *Guidance on PMCF plan template* ***MDCG 2020-8*** *Guidance on PMCF evaluation report template* *If PMCF is not considered applicable, this has to be duly justified.*	
Article 86	**Periodic Safety Update Report** (PSUR) Note: PSUR for class IIa, IIb , III		*Please follow the guidance laid down in the respective MDCG document, as soon as available*	

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EU Declaration of Conformity (19)				
Annex IV	**EC Declaration of Conformity**		*Please ensure that the (draft) declaration of conformity (DoC) contains all information as outlined in MDR, Annex IV.* *For initial reviews or new products, a draft DoC is required.* *For TD reviews of existing products, please provide the related signed copy of the DoC.*	