Annex A: Checklist for MDR Technical Documentation Submissions

This checklist contains the MDR requirements on the deliverables for MDR Technical Documentation (TD) Submissions. Please also follow the structured format when designing a MDR Technical Documentation. For further information please refer to the "Guidance for MDR Technical Documentation Submissions".

PLEASE USE THIS CHECKLIST AS FOLLOWS

- Columns with a grey header shall be completed by the manufacturer
  The right column "Completeness check by TÜV Rheinland" is exclusively for TÜV Rheinland use.
- Column "Page/Section of TD": please include the detailed location, in which the relevant MDR requirement is addressed in the Technical Documentation
- Column "Referenced Evidence (Document title & no., applicable chapter, section etc.) or in case of NA include justification": The black text on blue background is intended to give guidance and can be deleted, when completing this column
  - Please add the respective information for referenced evidences including the respective document title, document number, applicable chapter, section, page, etc.
  - Please ensure that the references are correct and the referenced evidence is attached
  - In case an individual requirement is not applicable, please indicate with "NA" and provide a justification. NA will be not accepted for mandatory requirements
- Please use the "Check off", when you have fully completed the respective section.
- TÜV Rheinland will perform a completeness check after submission using the right column of the table. The result will be communicated to the manufacturer.
- Please note that if the submission does not follow the MDR requirements or this checklist is not completed in an acceptable way, the TD Review will be delayed.

Table of Contents

1 Application

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	"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.		◯ available ◯ missing Comment
	Cover page(s) and table of contents of the TD		As part of the application, provide the cover page of the Technical Documentation. Please provide the detailed Table of Contents for Technical Documentation.		◯ available ◯ missing Comment
	Technical Documentation revision history		Please provide the revision history of the Technical Documentation, including reason for Technical Documentation revision.		◯ available ◯ missing Comment
	Presentation of Technical Documentation		Please ensure that the Technical Documentation is provided in a clear, organized, readily electronically searchable and in unambiguous manner.		◯ available ◯ missing Comment

2 Device Description and Specification

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.		◯ available ◯ missing Comment
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.		◯ available ◯ missing Comment
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.		◯ available ◯ missing Comment

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA 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.		◯ available ◯ missing Comment
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.		◯ available ◯ missing Comment
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.)		◯ available ◯ missing ◯ NA by client Comment
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.		◯ available ◯ missing ◯ NA by client Comment
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.		◯ available ◯ missing Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
1.1. (j)	General description of key functional elements (parts/components, formulation, composition, functionality and, where relevant, qualitative and quantitative composition)		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. physical/mechanical/electrical properties etc., compatibility with other products/accessories, etc. as well as clinical aspects.		◯ available ◯ missing Comment
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.		◯ available ◯ missing ◯ NA by client Comment
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.		◯ available ◯ missing ◯ NA by client Comment
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.		◯ available ◯ missing ◯ NA by client Comment
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.		◯ available ◯ missing Comment

3 Previous and Similar Generations of the Device

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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, post-market surveillance (PMS) and post-market clinical follow-up (PMCF).		◯ available ◯ missing ◯ N/A by client Comment
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.		◯ available ◯ missing ◯ N/A by client Comment

4 Labelling

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."

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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) (see Annex I, #23.2 and #23.3)		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. 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.		◯ available ◯ missing Comment
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.		◯ available ◯ missing ◯ NA by client Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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		◯ available ◯ missing ◯ NA by client Comment
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		◯ available ◯ missing ◯ NA by client Comment

5 Design and Manufacturing

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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. 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.		◯ available ◯ missing Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.		◯ available ◯ missing Comment
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		◯ available ◯ missing Comment
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. For critical suppliers/subcontractors, please include a justification for identifying the supplier as critical supplier. Please justify changes of subcontractors/suppliers, respectively.		◯ available ◯ missing Comment
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)		◯ available ◯ missing ◯ NA by client Comment

6 General Safety & Performance Requirements

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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, Common Specification 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.		○ available ○ missing Comment

7 Benefit-Risk Analysis and Risk Management

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
5. (a)–(b)	Risk Management: Risk management plan (Refer to Annex. I, #3a) 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 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. 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.).		◯ available ◯ missing Comment
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.		◯ available ◯ missing Comment

8 Pre-Clinical (Product Validation/ Performance) Data

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.

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	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.		◯ available ◯ missing ◯ NA by client Comment
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.		◯ available ◯ missing Comment
6.1. (a–b)	Chemical characterization		Please include the chemical characterization		◯ available ◯ missing ◯ NA by client Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.1. (a–b)	Biocompatibility including identification of all materials in direct or indirect contact with the patient and user Biological/ chemical tests/studies in animal models		The biocompatibility evaluation report shall be written by an expert in this field and shall document the test strategy and shall 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 are 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 lifetime. The referenced biocompatibility test reports need to be attached to the biocompatibility evaluation report. Please demonstrate the qualification of the personnel involved in the biocompatibility assessment (planning, execution, analysis).		◯ available ◯ missing ◯ NA by client Comment
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 is 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 nonionizing radiation.		◯ available ◯ missing ◯ NA by client Comment
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)		◯ available ◯ missing ◯ NA by client Comment
6.1. (a–b)	Software verification and validation including information on all of the different hardware configurations 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.		◯ available ◯ missing ◯ NA by client Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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. Simulated use tests may also include simulation of product life time.		◯ available ◯ missing ◯ NA by client Comment

9 Shelf Life / Transport Simulation

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 is 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.		◯ available ◯ missing ◯ N/A by client Comment
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”.		◯ available ◯ missing ◯ N/A by client Comment

10 Specific Cases – Devices Incorporating a Substance Considered to be a Medicinal Substance

Complete only if applicable. N/A ☐

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.		○ available ○ missing Comment
	Source of medicinal substance (including manufacturer)		Unequivocally identify the source of the medicinal substance.		○ available ○ missing Comment
	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.		○ available ○ missing Comment
	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.		○ available ○ missing Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	Usefulness of the substance as part of the device 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 usefulness of the substance as part of the device taking account of the intended purpose of the device, can be found.		○ available ○ missing Comment

11 Specific Cases – Devices Incorporating Materials of Animal Origin

Complete only if applicable. N/A ☐

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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		○ available ○ missing Comment
	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.		○ available ○ missing Comment

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	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.		◯ available ◯ missing Comment
	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?		◯ available ◯ missing Comment
	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.		◯ available ◯ missing Comment
	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.		◯ available ◯ missing Comment

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	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.		○ available ○ missing Comment

12 Specific Cases – Devices Incorporating Materials to be Absorbed by or Locally Dispersed in The Human Body

Complete only if applicable. N/A ☐

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.		○ available ○ missing Comment
	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.		○ available ○ missing Comment

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	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.		○ available ○ missing Comment
	Local tolerance		For the evaluation of local tolerance, please refer also to the requirements of Annex I to Directive 2001/83/EC.		○ available ○ missing Comment
	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.		○ available ○ missing Comment
	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.		○ available ○ missing ○ NA by client Comment

13 Specific Cases – Devices Incorporating Substances which are CMR or Endocrine Disrupting Substances

Complete only if applicable. N/A ☐

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.2.(d)	Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR) and/or endocrine disrupting substances		Please refer to MDR, Annex I # 10.4.1 to address the specific aspects related to CMR and/or endocrine-disrupting substances.		○ available ○ missing Comment
	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		○ available ○ missing Comment

14 Specific Cases – Devices with a Measuring Function

Complete only if applicable. N/A ☐

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.		○ available ○ missing Comment

15 Specific Cases – Combination, Connection to Other Devices

Complete only if applicable. N/A ☐

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 manufacturer. 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).		○ available ○ missing Comment

16 Specific Cases – Sterile Devices or Devices in Defined Microbiological Condition

Complete only if applicable. N/A ☐

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.1. (b)	Microbiological characterization: bioburden testing, pyrogen testing		Information on the biological contamination of the device needs to be provided, such as: - 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.		○ available ○ missing ○ NA by client Comment
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 is 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.		○ available ○ missing ○ NA by client Comment
	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.		○ available ○ missing ○ NA by client Comment

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	Validation of sterilization method		Key characteristics of the sterilization process and the related initial validation and all relevant revalidations including all 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.		◯ available ◯ missing ◯ NA by client Comment
	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.		◯ available ◯ missing ◯ NA by client Comment
	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.		◯ available ◯ missing ◯ NA by client Comment
	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.		◯ available ◯ missing ◯ NA by client Comment
	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.		◯ available ◯ missing ◯ NA by client Comment

17 Clinical Data

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.1. (c)	Clinical evaluation report and clinical evaluation plan		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 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 personnel conducting and approving the clinical evaluation and demonstrate their qualification including their product and procedure related expertise.		○ available ○ missing Comment
	Clinical investigation		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)		○ available ○ missing ○ NA by client Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	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)		Please provide - 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		○ available ○ missing ○ NA by client Comment
Article 32	Summary of Safety and Clinical Performance (SSCP) Note: SSCP for implantable devices and class III		Please follow the guidance laid down in MDCG 2019-9: Summary of safety and clinical performance		○ available ○ missing ○ NA by client Comment

18 Post Market Surveillance

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
Article 84	PMS plan		Refer to Annex III, #1.		○ available ○ missing Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.		◯ available ◯ missing ◯ NA by client Comment
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.		◯ available ◯ missing ◯ NA by client Comment

19 EU Declaration of Conformity

MDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 a copy of a recent signed DoC.		◯ available ◯ missing Comment

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