Medical Device Regulation (EU) 2017/745 Annex IX (Sections 2 & 3, 4 & 5) and Annex XI Part A technical documentation request form

This document has been developed to improve the assessment of the technical documentation by SGS NB 1639, allowing you, as the legal manufacturer, to check that you are providing us with complete documentation. This reduces the overall time spent by the notified body and noncompliance findings raised due to the documents not being located or incomplete. The template below is generally aligned with the assessment report and, therefore, can be used to support the Product Assessor to locate the information in a timely manner.

When submitting technical documentation for review, please consider the Team-NB summary of best practices for technical documentation: https://view.officeapps.live.com/op/view.aspx?src=http%3A%2F%2Fwww.team-nb.org%2Fwp-content%2Fuploads%2Fmembers%2FM2022%2FTeam-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-V1-final.docx. This document outlines the minimum expectations of notified bodies from the legal manufacturer for submitting technical documentation that aligns with MDR (EU) 2017/745, described in detail in Annexes II and III of Regulation (EU) 2017/745 and other relevant regulations and guidelines.

It should be noted that this report is not intended to cover MDR compliance itself, but only indicates the location of the information that demonstrates compliance with MDR.

General Note:

The technical documentation shall document how the manufacturer ensures compliance with every applicable GSPR, with supportive evidence, even if it is considered obvious. Where appropriate, the most recently updated comprehensive reports and data should be included. Reference to abbreviated or partial test reports is not considered acceptable.
Files should be provided via the SGS Delivering Office for upload into the SGS SharePoint system. The file path name should be no longer than 160 characters (and preferably significantly shorter). Please ensure that the filename bears a resemblance to the content for efficient navigation.

All reports and supporting evidence within the technical documentation must be in English, in a readable and searchable PDF format. If an original document is not available in English, a translation or other explanatory document should be provided alongside. Ensure that the data in the technical documentation is consistent and clear, with the data provided in the respective application forms.

There are some areas of the technical documentation that will require the duplication of information, such as device description or intended use. Please ensure that the information is correct and harmonized throughout all areas. This should also be considered when responding to nonconformities so that, even if the nonconformity is related to a single document, all other documentation that may be implicated should also be updated to avoid further queries.

It must be noted that, as a notified body, SGS is not allowed to consult nor make conclusions on the client's behalf. Valid justifications should always be provided in support of compliance with all the requirements, even if this appears to be obvious, and test report results should be interpreted, and conclusions drawn, appropriately. Where results are presented without appropriate analysis and conclusions, nonconformities are likely to be raised.

When completing this form, if a section is not applicable, please state NA and provide a justification.

EXAMPLE

Below is an example of requested information from Section 2.9 of this form. The tick boxes at the top indicate that such information is required for all types of devices and classifications.

Class I ☑ Class IIa ☑ Class IIb ☑ Class III ☑ Procedure pack (art 22) ☑

Possible response from the manufacturer is below.

SITES INVOLVED IN MANUFACTURING (ANNEX II.3.C)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
1. Listing of all sites that are used during the manufacturing of the devices. 2. Where external manufacturing or quality testing services have been used, justification of competency.	1. Manufacturing Flow Map PDF Rev 3 and Listing of Critical Subcontractors Rev 7 2. Contractor A: ISO 13485 certificate. Contractor B: ISO 17025 certificate	1a. Manufacturing Folder > Folder 3.6 > Manufacturing Flowmap Rev 3.docx 1b. Manufacturing Folder > Folder 4.2 > Listing of Critical Subcontractors Rev 7.docx 2. Manufacturing Folder > Folder 4.2> ISO 13485. pdf and ISO 17025.pdf

Please use the above example to assist in the completion of the following form.

1. ADMINISTRATIVE INFORMATION

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

ADMINISTRATIVE PARTICULARS (MANUFACTURER, PRODUCT AND TECHNICAL DOCUMENTATION)				
Company name and address			Basic UDI-DI(s) relevant to the product under review	Please consider MDCG 2018-1 when assigning Basic UDI-DI, considering intended purpose, risk class and essential design and manufacture.
Name of technical documentation and product subject to review	Please define the technical documentation here. If there are devices included in the technical documentation that are not intended to be reviewed, please clearly detail these here (by name or other references, such as basic UDI-DI), with a declaration that the data for the subject device can be easily extracted from the other device data. If there are any devices supplied together in a kit that are covered by other technical documentation in the same contract, please detail these devices here, concerning the basic UDI-DI and model numbers that are common to other planned technical documentation reviews.		Medical device name and model under review	Please list all variants of the device(s) in the range covered by the review.
Codes	MDA/MDN/MDS:	EMDN:	Classification and rule:	
Cover letter and other relevant information	Please describe why this technical documentation is submitted to the Notified Body. This should include the technical documentation name and device's basic marketing history (including if it is already CE marked and, if so, the date the certificate was first issued). For example: a. New MDR application for Class I, IIa, IIb or III device, not previously CE marked (cleared under FDA in 2012) b. New product variant based on existing approved product, previously CE marked under MDD since 2008 (ref certificate xxx) c. Change to product, not previously CE marked, no market history or PMS in any territory d. Renewal of technical documentation certification, ref certificate xxx e. Routine sample audit of Class IIa or IIb devices, ref certificate xxx			
Checklist completed by the legal manufacturer	Name: Email address:		Date (legal manufacturer):	European date format: dd.mm.yy
Checklist verified by (SGS Delivery Office)	Name: Email address:		Date (SGS delivery office):	European date format: dd.mm.yy

2. GENERIC INFORMATION

2.1. DESCRIPTION OF PRODUCT ON SGS CERTIFICATE AND DECLARATION OF CONFORMITY (ANNEX II)

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	DESCRIPTION OF THE PRODUCT ON THE SGS CERTIFICATE	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. List of all variants (sales and marketing reference / catalogue number / trade name) related to the device(s) under review		
	1. Basic UDI-DI (all different basic UDI-DIs covered by this assessment)		
B	**DECLARATION OF CONFORMITY (ANNEX IV)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Declaration of conformity (draft if appropriate)		

2.2. PRODUCT DESCRIPTION (ANNEX II)

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	GENERIC PRODUCT DETAILS	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Details of any associated technical specifications, such as features, dimensions and performance attributes, of the device and any variants / configurations and accessories that would typically appear in the product specification		
	2. Details and justifications of any novel features defined in the technical documentation, as well as in the marketing literature and on the website		
	3. Descriptions of the families of different devices. If these are intended to be covered within the same review, justification in terms of similar indications, intended use, design and manufacture, technologies, etc		
	4. Clear description of the device detailing variants if there are multiple devices		
	5. Description of the general device type, range of devices (number of variants, sizes, product codes, etc.), or different types of similar devices included within submission		
	6. Summary of the materials of construction		

B	SIGNIFICANT CHANGE TO AN EXISTING DEVICE	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE
	1. Listing of all significant changes since **the product was released to the market**		
	2. Rationale/justification for the change		
	1. Listing of all significant changes **since the product was last reviewed by SGS (if applicable)**		
	2. Confirmation that each significant change has been formally communicated to SGS and the outcome of any resulting review (e.g. notification of change form submitted to SGS or other relevant Notified Body)		
	3. Confirmation (justification) of whether the change falls within the existing scope of product certification		
C	**PREVIOUS AND SIMILAR GENERATIONS (ANNEX II.1.2)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Overview of all previous generations of the device produced, if and as applicable		
D	**MARKET HISTORY**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. As applicable per MDR Annex II Section 1.2, details of global marketing and when regulatory approval was obtained for each region		
E	**PRINCIPLE OF OPERATION AND ITS MODE OF ACTION AND CORE PERFORMANCE CLAIMS (ANNEX II.1.1.D / ARTICLE 7)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Principle of device operation / mode of action		
	1. Manufacturer website address, marketing literature (e.g. brochure), as applicable		
F	**KEY FUNCTIONAL ELEMENTS (ANNEX II.1.1.J)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. General description of the key functional elements, and description of parts / components (including hardware and software if appropriate) of the device, their formulation, composition and functionality		
	1. Graphical representation of the device with sufficient explanation to understand the imagery (as applicable)		

G	DEVICE USED IN COMBINATION (ANNEX II.1.1.H)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE
	1. Description and risk classification of each accessory of the device and associated marketing information (e.g. if CE marked or going to be CE marked by a Notified Body)		
	2. Description of all other medical devices and products that are not medical devices, but are intended to be used in combination with the main device		

2.3. UNIQUE DEVICE IDENTIFICATION

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	UDI (ANNEX VI PART C)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Identification of basic UDI-DI and clarification if the relevant data has been provided to the UDI database in EUDAMED		
	2. Identification system of the product and its variants and accessories (all unique basic UDI-Dis covered by this technical documentation should be documented)		
	3. If the device is reusable, confirmation that the device directly bears the UDI carrier, or justification why not		
	1. Procedure that refers to the location of basic UDI-DI within the technical documentation, including, PSUR, implant card and Manufacturer Incident Reports, as appropriate		
B	**UDI-DI / UDI-PI (ANNEX VI PART C)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Identification of UDI-DI and confirmation if the relevant data has been provided to the UDI database in EUDAMED		
	2. Identification of UDI-PI and explanation of its structure		
	1. Procedure that refers to the location of UDI-DI and UDI-PI within the technical documentation, including device, labels, packaging, etc., as appropriate		
	1. Descriptions of any changes to UDI-DI, if applicable		

2.4. MEDICAL DEVICE JUSTIFICATION, CLASSIFICATION (ARTICLE 2, ANNEX II AND ANNEX VIII)

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	MEDICAL DEVICE DEFINITION (ARTICLE 2)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Justification that the device qualifies as a medical device under MDR Article 2		
B	**INTENDED USE AND INTENDED USERS (ANNEX II.1)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Intended purpose		
	2. Clinical indications of use		
	1. Contra-indications		
	1. Patient population		
	2. Clinical condition(s) to be diagnosed or treated		
	1. Intended users		
	2. Intended use environment		
C	**CLASSIFICATION (ANNEX VIII)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Justification for device risk classification, including rule		
	2. Justification if the device is to be considered well-established technology		
	3. Justification if the device is considered to be borderline, please provide a rationale		

2.5. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS APPLICABLE TO THE DEVICE / REVIEW

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	(ANNEX I)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. GSPR compliance rationales (e.g. GSPR matrix) (Note that links / references to supporting evidence must be as specific as possible, a generic response like "risk analysis" may not be acceptable in terms of traceability)		
B	**MACHINERY DIRECTIVE 2006/42/EC (ARTICLE 1)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Compliance with the Machinery Directive, if applicable		

2.6. STANDARDS RELEVANT TO THE DEVICE / REVIEW

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	STANDARD / COMMON SPECIFICATIONS USED	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Listing of utilized common specifications (Article 9), harmonized standards, or other standards, including revision level		
	2. Clear identification if the standards are used in full or in part		

2.7. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	RISK MANAGEMENT (GSPR 3 AND ANNEX II.5)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Risk management documentation (risk management plan, risk analysis, overall residual risk evaluation, control measures to reduce risk, risk management review report, post-production and post-market activities)		
	2. Compliance with risk management standard(s), if any		
	3. The frequency of updates		
	4. Systems for risk estimation and risk acceptability. If not clearly described in the output technical documentation, please reference the governing SOPs)		

	1. Identification of the risk management team		
	2. Justifications for the competency of the risk management team		
B	**RA METHODOLOGY AND RISK MANAGEMENT PLAN (GSPR 3, 4, 5)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Risk management strategy, including coverage of the full product life cycle		
	1. Risk management plan		
	2. Records of and justifications for changes to the risk management plan		
	1. Identification of characteristics related to safety, including usability		
	2. Identification of hazards or hazardous situation		
	3. Design risk assessment and individual benefit / risk analysis and risk control measures		
	4. Production risk assessment and individual benefit / risk analysis and risk control measures		
	5. Risk assessment and individual benefit / risk analysis before and after risk control measures		
	6. Overall benefit / risk analysis and acceptability		
	1. Safety and effectiveness demonstration during lifetime and intended use (including storage, transport conditions, etc.) of the device		
	1. Incorporation of post-production / post-market experience into the risk management system		
	1. Risk management report and conclusion		

2.8. DEVICE VERIFICATION AND VALIDATION

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	**DEVICE DESIGN STAGES (ANNEX II.3/ GSPR 10/ GSPR 14)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE** Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Design stages have been applied (as per MDR Annex II Section 3), covering all ranges of products		

	1. Design inputs and their relationship to the design outputs (e.g. traceability matrix)		
	2. Safety and performance characteristics, including interaction with other devices, if applicable		
	3. Performance claims		
	4. Verification and validation reports that are intended to demonstrate support safety and performance associated with claims		
	5. Competency of providers of design services		
	1. Test protocols, including statistical justifications, where appropriate		
	2. Test reports, including deviation justifications, where appropriate		
	3. Competency of providers of test services		
C	**COMPATIBILITY WITH SUBSTANCES (FLUID/DRUG DELIVERY), DEVICES USED TO DELIVER MEDICINAL SUBSTANCES (GSPR 10.3)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Substances that come into contact with the device, including gases, fluids, body tissues, etc.		
	2. Compatibility of the device with those substances		
	3. For the device that is intended to deliver medicinal substances, evidence of compatibility with medicinal substances delivered		
D	**COMPATIBILITY (GSPR 14.1)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Identification of devices or equipment intended to be used in combination		
	2. Safety and performance of the whole combination (including the connection system, including fluid, gas transfer, electrical or mechanical coupling, as appropriate). If the device is to be connected to another system(s), evidence of the compatibility with the combination of any external hardware / software)		

E	SOFTWARE	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE
	1. Relevant details related to software Note: Please be aware this section refers to both stand-alone as well as incorporated software / firmware		
	1. Clarification if artificial intelligence (AI) or machine learning have been incorporated into the device		
	2. Identify the functionality and intended use of AI		
	3. Evidence related to the design and evaluation of the AI module(s)		
F	**CLASS 1R (REUSABILITY ASPECTS)**	**DOCUMENT TITLE/S AND REVISION LEVEL** For sterile device(s) – if the products are supplied sterile or non-sterile, then please use sterilization section 4	**LOCATION/S OF THE EVIDENCE**
	1. Reusability protocol and reports for all IFU claims, covering the maximum number of reuses and sterilization cycles, if sterile		
	2. Process for cleaning		
	3. Reusability parameters		
	4. Residual tests, if applicable for the disinfectants used		
	5. Functionality Protocol and report: Product functionality test, covering the maximum number of usage, as per IFU for all devices, unless otherwise worst is justified, including the maximum number of reuses and sterilization cycles, if sterile		
G	**CLASS 1M (MEASURING ASPECTS)**	**DOCUMENT TITLE/S AND REVISION LEVEL** For sterile device(s) – if the products are supplied sterile or non-sterile, then please use sterilization section 4	**LOCATION/S OF THE EVIDENCE**
	1. Measuring units as per the claim		
	2. Protocol and reports for measuring function verification for all devices within the technical documentation		
	3. Measuring parameters		

2.9. DEVICE MANUFACTURING INFORMATION

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	SITES INVOLVED IN MANUFACTURE (ANNEX II.3.C)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Description of manufacturing processes (including whether internal or subcontracted etc.)		
	2. Listing of all sites that are used during the manufacturing of the devices		
B	**SUBCONTRACTED ACTIVITY AND TESTING FACILITIES**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. List the activity subcontracted and used for testing e.g., for production, testing, sterilization		
	2. Name and address		
	3. Justification of competency i.e. QMS certificate		
	4. Agreement		
C	**MANUFACTURING OF THE DEVICE**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Evidence showing that the processes are supported by appropriate validations, or other		
	2. Evidence showing that the design and manufacturing process of the device adequately addresses physical, environmental (plus use-environmental), reciprocal interference risks and risk of unintentional ingress of substances into the devices		
	1. As appropriate, a graphical representation to enable the manufacturing and QC processes, including outsourced activities, to be more clearly understood		
D	**DESCRIPTION OF MANUFACTURING ENVIRONMENTAL CONDITIONS AND THEIR CONTROLS, IF APPLICABLE**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Evidence of controlled environment		
	2. Evidence of the classification of the controlled environment, i.e. physical and microbial validation and the frequency and limits		
E	**DEVICE CLEANLINESS AND CONTROLS, IF APPLICABLE**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Cleanliness requirements for the finished device		

	2. Process for cleaning		
	3. Cleaning parameters		
	4. Cleaning agents		
	5. Worst-case justification		
	6. Cleaning procedure		
	7. Cleaning validation protocol and reports		
	8. Residual tests, if applicable for th disinfectants used		

2.10. MATERIALS AND BIOLOGICAL RISK EVALUATION

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	DEVICE CONSTRUCTION – RAW MATERIALS (ANNEX II.1.1.K)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Materials of construction		
	2. Materials of construction in direct or indirect contact with the body, including plasticizers, if applicable		
	3. Utilization of standards or chemical constitution if no standard is applicable		
B	**SUBSTANCES (ANNEX I GSPR 10.4)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Responses to each indent of Annex I 10.4.1, as applicable		
C	**USE OF ALTERNATIVE SUBSTANCES (GSPR 10.4.2)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Responses to each indent of Annex I 10.4.2, as applicable		
D	**BIOCOMPATIBILITY (GSPR 10)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Overview of the biocompatibility strategy (testing and/or literature review) and methodology utilized, including the use of ISO 10993-x		
	2. Overview of technical documentation, including linkage with risk management documentation		

	3. Competency of external providers of test services		
	4. Justification for biocompatibility following design or manufacturing changes		
	5. Gap analyses or other solutions that may be required for testing performed, utilizing standards that are now superseded		
	1. Bio-classification per ISO 10993-1		
	1. Justification of competency for authors / contributors (including third-party laboratories, as applicable)		

2.11. PACKAGING AND SHELF LIFE (GSPR 6, GSPR 7, 10.2, 11.3, 11.4)

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	PACKAGING INTEGRITY AND SHELF LIFE	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Claimed shelf life and evidence, i.e. written evidence and justification with an example of the actual batch label		
	2. Overview of evidence for safety and performance of the device at each stage of the life cycle		
	3. Applicable standards used related to the shelf life of both the packaging integrity and functional testing		
	1. Description of primary and secondary packaging for all devices covered under the technical documentation		
	2. Certificates / COA for the packaging materials used and evidence of the compatibility with the chosen packaging type		
	3. If a significant change has occurred, provide justification for continued validity of shelf life		
	1. Name and address of the testing facility		
	2. Accreditation certs for the testing facility		
	1. Protocol for the accelerated aging packaging test		
	2. Accelerated aging packaging integrity test reports with the actual data		
	1. Protocol for the real-time aging packaging integrity test		
	2. Real-time aging packaging integrity test reports and actual data or real-time aging plan		

	1. Protocol for the functionality test covering the life of the device		
	2. Reports for functionality test covering the life of the device		
	1. Justification for transport conditions and associated test types		
	2. Justification for storage conditions		
	3. Protocol and test report for transit testing covering the standard storage and shipping conditions, product functionality and packaging test, post-transit tests, etc.		

2.12. LABELLING AND INSTRUCTIONS FOR USE

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

A	CONTENT OF LABELING AND INSTRUCTIONS FOR USE (GSPR 23.1)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Evidence showing that each device under review is accompanied by appropriate information		
	1. Example of label per device for all packaging levels (template)		
	1. Batch label examples (per device) for all packaging types, i.e. primary, secondary…		
	1. Justification for IFUs not being required, if applicable		
	1. As applicable, description of the strategy for electronic IFUs, compliance with applicable regulation		
	1. Use of harmonized symbols, as appropriate		
	2. Explanation for the use of other symbols, as applicable		
	1. Identification of market countries (where the product is sold)		
	2. Identification of required languages for market countries		
	3. Verification / validation of translations (on all applicable labels / IFUs)		
	4. Competency of the translators and translation procedure		

B	IMPLANTABLE DEVICES – IMPLANT CARD (ARTICLE 18)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Implant card requirement, or justification if not needed		
	1. Physical dimensions of implant card (per MDCG 2021-11)		
	1. Languages included on the implant card		
	2. Justification for the languages on the implant card		

2.13. NANOMATERIALS (RULE 19 ANNEX VIII MDR (EU) 2017/745)

Class I ☐ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☐

	NANOMATERIALS (RULE 19 ANNEX VIII MDR (EU) 2017/745)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	Justification if not applicable OR Description with justification for the use of nanomaterials (including compliance with Annex I 10.6) and other supportive documentation		

2.14. SUBSTANCES ABSORBED BY OR DISPERSED IN THE HUMAN BODY RULE 21 ANNEX VIII MDR (EU) 2017/745

Class I ☐ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☐

	SUBSTANCES ABSORBED BY OR DISPERSED IN THE HUMAN BODY (RULE 21 ANNEX VIII MDR (EU) 2017/745)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Description of the use of materials, wholly or mainly absorbed, or locally dispersed, in the human body or intended to undergo a chemical change in the body, if applicable		
	2. Listing of relevant scientific opinions / regulatory approvals		
	1. Confirmation that any proposed significant change to the material was already granted relevant regulatory approval in advance, if applicable		

2.15. DEVICES MANUFACTURED UTILIZING TISSUES OR CELLS OF ANIMAL ORIGIN OR DERIVATIVE (IF APPLICABLE)

Class I ☐ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☐

	ANIMAL TISSUE (ANNEX II 6.2)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page
	1. Description of animal tissue / derivative used and its intended purpose (including species)		
	2. Details of approval history		
	1. Principle of operation and mode of action relevant to animal tissues		
	2. Performance claims		
	1. Manufacturing information related to animal tissues		
	2. Associated flow diagram, demonstrating incoming, in-process and final inspection		
	3. Manufacturing process validation		
	1. Clarification, if Regulation 722/2012 is applicable, and associated justification		
	2. Applicability of ISO 22442 and relevant compliance documentation. Complete the section below if ISO 22442 is applicable		
	1. Nature and source of material including geographical origin		
	2. Route of administration and quantities		
	3. Veterinary controls in place or alternative justification		
	4. Processing controls, preservation and testing and handling		

2.16. DEVICES CONTAINING MEDICINAL SUBSTANCES (IF APPLICABLE)

Class I ☐ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☐

	MEDICINAL SUBSTANCES (ANNEX II 6.2)	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Description of all medicinal substances		
	2. Details of approval history		
	1. Principle of operation and mode of action relevant to the medicinal substance		
	2. Performance claims		
	3. Usefulness justification		
	1. Manufacturing information related to the medicinal substance		
	2. Associated flow diagram demonstrating incoming, in-process and final inspection		
	3. Manufacturing process validation		
	1. Confirmation that the devices fall under MDR (2017/745) and not 2001/81/EC		
	2. Benefit-risk analysis of medicinal substance		

3. CLINICAL EVALUATION REPORT (BEST PRACTICE)

Class I ☐ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☐

3A	CLINICAL EVALUATION PLAN	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. New device: content aligns with MDR Annex XIV Part A		
	2. Legacy device: content aligns with MDCG 2020-6 Appendix II		

3B	CLINICAL EVALUATION REPORT	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. With version controlled, dated and signed		
	2. Include CVs and declaration of interest of authors		
	3. Table of contents with page number		
	4. Content following MEDDEV 2.7/4 Rev 4 Section A9		
	5. Information regarding the device under evaluation can be clearly identified, if the CER included several devices		
3C	**CLINICAL DATA/EVIDENCE – EU MDR ARTICLE 61**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Description of clinical performance and identification of clinical data/evidence related to the performance of the device under review		
	2. Description of clinical safety and identification of clinical data/evidence related to the safety of the device under review		
	3. Justification of the level and sufficiency of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements		
3D	**LITERATURE SEARCH PROTOCOL AND REPORT**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Included in the CER or separate documents		
	2. Copies of the full text of selected articles		
3E	**CLINICAL INVESTIGATION**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	If performed: 1. Clinical investigation plan		
	2. Clinical investigation report		
	3. Evidence of regulatory approval of the study		
	4. Evidence of ethics committee approval		
	5. Copy of any publication of the clinical investigation, if the study is published		
	1. If not performed for Class III or implantable devices, the justification provided in the CER		

3F	PMS AND PMCF	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	PMS plan and PMCF plan 1. PMS plan provided, according to MDR Annex III, which follows the PMS system of the manufacture (MDR Article 83).		
	2. PMCF plan, according to the requirements of MDR Annex XIV Part B		
	3. PMCF plan, following the template MDCG 2020-07		
	4. Justification, if no PMCF plan is provided		
	PMCF evaluation report: 1. Not applicable for a new device		
	2. Following the template of MDCG 2020-08		
	PSUR (for Class II and III devices) 1. Following MDCG 2022-21 PSUR guidance and template		
	2. Submit every year after MDR certification for Class III and IIb implantable devices, every 2 years for Class IIa implantable devices		
3G	**SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. For implantable device and Class III devices guidance MDCG2019-09		
3H	**JUSTIFICATION FOR EXEMPTION FROM CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP)**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. For Class III implantable devices or Class IIb Rule 12 devices (MDR Article 54) Guidance MDCG 2019-3 Rev 1		

4. STERILIZATION FOR STERILE AND/OR NON-STERILE TO BE STERILIZED BY END USER

Class I ☑ Class IIA ☑ Class IIB ☑ Class III ☑ Procedure pack (art 22) ☑

4A	STERILIZATION FOR THE PRODUCT SUPPLIED STERILE	DOCUMENT TITLE/S AND REVISION LEVEL	LOCATION/S OF THE EVIDENCE Client to indicate folder name(s) / filename(s) / chapter(s) / page number(s), document revision(s), as applicable
	1. Confirm the sterilization method, i.e. EO, irradiation, steam, aseptic, hydrogen peroxide, others		
	1. Applicable standards related to the sterilization process		
	1. SAL claimed		

	1. Sterilization procedures – Sterilization, bioburden, endotoxin, sterility test, environmental control procedures covering limits, frequency, revalidation, etc.		
	1. Family name / worst-case – justification for family and selection of worst-case product for sterilization validation and processing categories, as required by individual sterilization standard requirements, i.e. family name, variants selected, worst-case product selection for sterilization and justification		
	1. Bioburden testing – validation of test method, as per ISO11737-1 and two most recent bioburden results		
	2. Endotoxin testing – and 2 most recent results. If not, provide justification for not doing one		
	3. Sterility test and results/reports		
	1. Sterilizing agent with concentration, if applicable		
	1. Confirm the microbicidal effectiveness of the sterilization agent used		
	1. Material effects of the sterilizing agent – evidence of the effects of the sterilizing agent on product composition, material, packaging, etc. including multiple cycles		
	1. Environmental considerations of the sterilizing agent – if applicable, please provide evidence, i.e. could be a risk assessment of the sterilizing agent on the environment.		
	1. Protocols-validation, revalidation		
	2. Reports -validation, revalidation		
	3. IQ, OQ, PQ, if applicable		
	4. PCD-IPCD, EPCD		
	5. Cycle data		
	6. For EO: EO residuals report, information on EO gas specification and certificate, biological indicators / chemical and certificate, PCD-IPCD, EPCD		
	Additional evidence based on the type of sterilization method used- 1. EO – EO residuals report, information on EO gas specification and certificate, biological indicators / chemical and certificate, PCD-IPCD, EPCD		
	2. Irradiation – protocols and dose-mapping report min-max dose – calibration details/certs of the dosimeters used Protocol and dose-setting / dose substantiation method 1, VDmax. Method 2 original validation report Dose audit data trend and the two most recent dose audit reports, if the frequency of dose audits is reduced, then justification for the reduction		
	3. Steam - biological indicators / chemical and certificate		

	4. Aseptic -– justification of the use of this method, media fills initial PQ, media fill periodic performance requalification PRQ report, media selection and growth support, a certificate for the filter used and validation of fluid-specific microbial retention by filters, certificates of the sterilized equipment used		
	5. Others – i.e. hydrogen peroxide, dry heat, chemical sterilization, chlorine dioxide, etc.		
4B	**STERILIZATION VALIDATION FOR PRODUCT TO BE STERILIZED BY END USER**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Details of the products supplied non-sterilized and sterilized by the end user, as per IFU claims		
	2. Worst-case justification		
	3. Sterilization validation as per IFU		
	4. Cycle parameters, protocols – validation, revalidation, as per IFU claim, reports – validation, revalidation as per IFU claims, cycle data, residuals report, if applicable		
4C	**ASSESSMENT OF CHANGES**	**DOCUMENT TITLE/S AND REVISION LEVEL**	**LOCATION/S OF THE EVIDENCE**
	1. Assessment of changes that could affect the current sterilization validation / end-user validation and process, i.e. product, packaging, raw materials, manufacturing process, design, sterilization, etc., as per relevant sterilization standard requirements		