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in progress

MDR Documentation Submission

Best Practice Guidelines

Contents

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Introduction

Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annex IX to XI of (EU) 2017/745 (MDR). Subject to classification and conformity assessment route chosen, devices of classification IIa and higher (except for custom-made devices) will need their technical documentation assessed by the Notified Body.

This Technical Documentation Submission Guidance is aligned to the requirements of (EU) 2017/745 Medical Devices Regulation (MDR), described in detail in Annexes II and III of (EU) 2017/745.

Note: for combined submission MDR and UKCA the manufacturer shall provide:

- Draft UKCA DoC
- Draft UKCA IFU
- Draft UKCA Labelling
- UK Responsible Person
- UK Designated Standards
- UKCA ER checklist
- UKCA Device Classification

Notified Body BSI Group The Netherlands B.V. (2797) and medical device manufacturers both have an interest in speeding up the review of Technical Documentation (as part of initial approvals, substantial change approvals, renewal applications etc.) and reducing time to issue certification.

The most common reasons for delays in technical documentation reviews are:

- **Incomplete submissions**
  BSI has not been provided with all the information needed for the review.
- **Poor structuring of Technical Documentation**
  The information is present within the technical documentation but is difficult to locate.

To reduce the frequency of the above issues, BSI Medical Devices proposes the present Best Practice Guidelines for MDR Documentation Submission.

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Submission and Technical Documentation content

Three things are required for any technical documentation review:

- Context (i.e., an explanation of what is being requested and why).
- The Technical Documentation (i.e., objective evidence to demonstrate compliance).
- Authorisation for BSI to carry out the work.

The submission should therefore contain:

1 Cover letter

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

- Certificate # reference(s) (if known).
- The type of review (new product, design change, shelf-life extension, etc.).
- Brief product description, including model numbers involved, etc.
- BSI Ref. # (Service Management Orders SMO #) for any other relevant submissions (for example, concurrent applications which may affect the submission)
- An explanation of:
  - What has been submitted and how it demonstrates compliance,
  - Details of where and when the subject device was previously assessed with BSI reference number, and, for changes to existing certification:
    - What is affected (packaging, material change, sterilisation, etc.)
    - What is not affected (along with appropriate justification).

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2 The Technical Documentation

MDR is a new legislation and for initial approvals, a complete submission with all the relevant technical documentation included is required even if the device was previously certified under the MDD or AIMDD.

To assist manufacturers in determining the correct information to provide to BSI, a comprehensive checklist of various documents required to be submitted as part of Technical Documentation can be found in the BSI Completeness Check form. Guidance on each of the items requested in the Completeness Check form can be found in Appendix A of this document. Additional guidance may be found in reference documents listed in Appendix B. When referring to Appendices A and B, please note that the listed standards are for guidance purposes only; these are not mandated by BSI.

For submissions in the context of scope extensions or substantial change approvals, as far as is practical, submissions should be "stand alone" and not refer to previous submissions for evidence of compliance. The reason is that the reviewer must assess the documentation in the context of the intended submission and confirm that it is still relevant within this context. If a submission draws upon information previously submitted to BSI, please include the relevant report or document which demonstrates compliance, rather than directing the reviewer to the earlier review. This will save time (e.g., in finding the report, confirming that the correct report has been found, confirming whether there have been any changes affecting its relevance to the current application, etc.).

3 Authorisation for work to be conducted

A signed approved quote will be required before work can commence. If this is not already in place, please contact your BSI Scheme Manager or BSI Sales Team.

4 Change Notification Form

If the submission is for a change to an existing, valid certificate, a completed BSI Change Notification form (MDF4900) will be required with the submission. If there is a significant change while an application and/or technical documentation assessment is in process, a Change Notification Form (MDF4900) will be required.

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Submission method

- The preferred route for submissions is via the secure **BSI Electronic Client Portal.** If you do not have access to the BSI document upload portal, please contact your Scheme Manager or their administrative support to request for this to be set up for your company.
- If the above method is not suitable or does not work, please contact your BSI representative to discuss alternate methods of document submission. Please note that documents submitted via any alternate methods will need to be uploaded to our electronic document management system by our administration team, which may add time and cost to the review.
- We **do not accept** hard copies of technical documentation.

Document format

Language

All submitted Technical Documentation and test results must be in the English language. Exceptions may be allowed in the case of voluntary change of Notified Body (Transfer from another Notified Body to BSI). Please contact the BSI Account Manager or your BSI Scheme Manager for further details in case of Transfers.

Electronic file format

Format and file size limits

- Documents should ideally be provided as paginated, fully searchable bookmarked PDF files (see below for further information on text recognition and bookmarks). Other software formats may be acceptable, but again, these files will need to be converted to PDF files with bookmarks, which will add time and cost to the review. Significant delays may result if files cannot be easily converted to this format.

- The following types of submission formatting can create review inefficiencies as well as incompatibility with BSI IT systems and should be avoided:
  - PDF files and attachments should not be file protected or locked as this prevents necessary access and file manipulation for archiving.
  - Use of zip files or multiple layers of zip files.
  - Use of many separate pdf documents.
  - Use of low quality scanned documentation where data cannot be easily extracted.
- File/bookmark names should be logical and reflect the information covered within that part. File names should then be cross-referred to in the BSI Completeness Checklist.
- Documents should be bookmarked to ensure ease of navigation (see below for more information relating to bookmarking). When files are not organised properly, review time and the timeline for achieving certification may be increased significantly due to difficulty in locating evidence to verify compliance.
- **It is strongly recommended that one PDF file is submitted for each part specified in the table overleaf.** If this is not possible due to file size (pre-clinical information for example) consider breaking it down into the smallest number of logical sub-sections possible.

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Parts	MDR Cross-references	Cross-reference to BSI Completeness Check Form
Part A - Device Description and Specifications including variants and accessories	Annex II, Section 1	Section 4.2, Part 1
Part B - Information to be supplied by the manufacturer	Annex II, Section 2	Section 4.2, Part 2
Part C - Design and manufacturing information	Annex II, Section 3	Section 4.2, Part 3
Part D - General safety and performance requirements	Annex II, Section 4	Section 4.2, Part 4
Part E - Benefit-Risk Analysis and Risk Management	Annex II, Section 5	Section 4.2, Part 5
Part F - Pre-clinical Information (If this section contains a substantial amount of information, it is recommended to break it down into logical smaller sub-sections)	Annex II, Sections 6.1.a, 6.1.b, 6.2.d, 6.2.f	Section 4.2, Parts 6.1-6.5; 6.11, 6.12, 6.15 – 6.17
Part G - Clinical Evaluation, PMS and PMCF	Annex II, Section 6.1.c, 6.1.d; Annex III	Section 4.2, Parts 6.6, 6.7
Part H - Information related to • Medicinal Substances incorporated in the device • Animal/Human tissue derivatives or cells or other non-viable biological substances • Substances absorbed by or locally dispersed in the human body (for Rule 21 devices)	Annex II, Section 6.2.a – 6.2.c	Section 4.2, Parts 6.8 – 6.10
Part I - Sterilisation and Information related to re-usable surgical instruments	Annex II, Section 6.2.e	Section 4.2, Parts 6.13, 6.14
Part J - Declaration of Conformity	Annex IV	Section 4.2, Part 6.18
Part K - Specific information for Class III implantable devices, and Class IIb active devices intended to administer or remove medicinal substances as per Rule 12 to determine the need for CECP process	Article 54	Section 5

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Optical character recognition (searchable format)

- Manufacturers scanning directly from printed pages should utilise Optical Character Recognition (OCR) so that as much of the resultant PDF file is searchable as possible.
- Non-searchable submissions will be subjected to OCR conversion adding review time.

Bookmarks

- Bookmarks are requested to aid in locating individual sections of the technical documents. At a minimum, sections in MDR Annex II "Technical Documentation" (or the GHTF STED sections) should be bookmarked, as well as any supporting attachments referenced to within the main body of the technical documentation.
- Sometimes random bookmarks based on document headings and subheadings are created when documents are converted to PDF format. These bookmarks should be edited to provide clear document references and to remove excessive, unnecessary or confusing bookmarks.

Clear organization and easy navigation will make it easier to find documents and will therefore reduce overall time required for the review.

Signatures

Signatures are required for any signed document in the file, including signed quotes and BSI Work Authorisation Forms. Signatures can be handled in several ways:

- Documents may be digitally signed.
- Signature pages can be scanned in and inserted into the electronic document.
- A "marker page" can be inserted into the document indicating that the signatures have been provided separately to BSI electronically. BSI will scan and insert these pages into the file, logging the time to do so.
- All protocols/reports which require approval (as per the legislative requirements and manufacturer's own procedures and policies), except for the Declaration of Conformity, must have undergone those requisite approvals and be submitted with evidence of those approvals (typically through dated and signed reports, signed protocols, or evidence of approval in an electronic system etc.).

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Submission process

The following is an overview of the submission process:

a Notify BSI that you have an application for review. For new clients, this will generally be via a member of the **sales team**. For existing clients, this will be your Scheme Manager, or a member of the administration team. Email and phone are the preferred means of contact.

b For initial MDR work, a formal quotation will be required.

c Once the signed approved quote (see Section 2.3 above) has been submitted, BSI will assign the relevant certificate references and/or unique identification number ("SMOxxxxxx") (i.e., Service Management Order number) for your review and contact you with those references. We ask that you reference those numbers during document submission via the BSI portal or in any email correspondence with BSI during the review process.

d Manufacturers are encouraged to complete a MDR completeness check prior to the start of the detailed review. This ensures all documents needed to initiate the review have been included as part of the technical documentation submission (Appendix A). This ensures much of the first round of questions is not used to ask for key missing information. The requirement for this can be discussed with your Scheme Manager following quote approval.

e The conformity assessment of the technical documentation review can be planned upon receipt of a signed quote together with all required application documentation (per Annex IX for initial submissions) and BSI acceptance of the MDR completeness checklist, where appropriate.

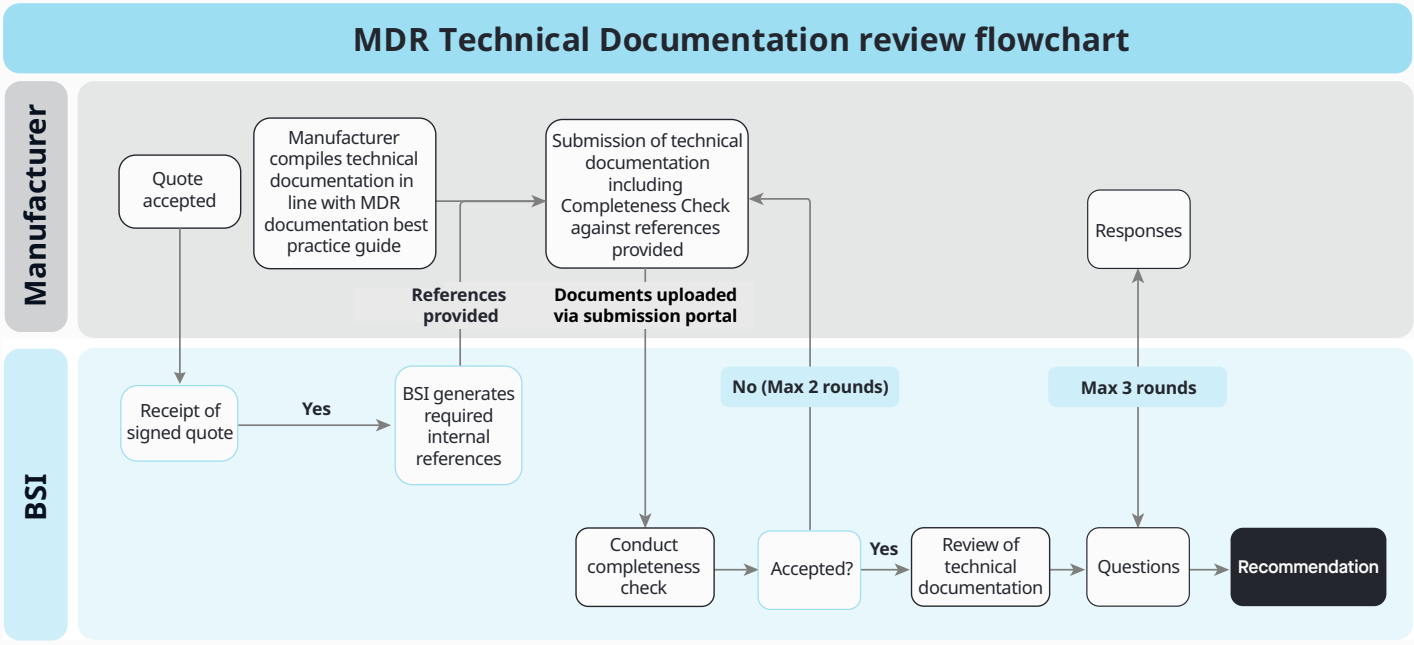

Figure 1: MDR Technical Documentation Review Flowchart.

Note: recommendation can result in either certification or refusal.

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Additional topics to consider when preparing Technical Documentation for submission

Manufacturer personnel support

Please ensure appropriate manufacturer resources (RA, QA, R&D, Manufacturing, etc.) are available during technical documentation review. The faster information can be provided, the faster questions can be closed to progress towards certification.

Document availability

If a document includes hyperlinks or cross-references to other documents or embedded documents, ensure that these are functional, and all the documents are available.

Languages

As part of the quality system, or of the documents defining the manufacturing process, the manufacturer should have procedures for ensuring accurate translation of labelling, instructions for use, product claims in marketing materials, SSCPs etc. These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation, or the SSCPs, where inaccurate information may be presented to the end users or patients through inadequate translation.

Certificate scope

Sometimes the addition of new products, or even changes to existing products, can affect the scope of the associated Quality System certificate (e.g., Annex IX Chapter I & III QMS certificate or Annex XI Part A EU Quality Assurance certificate). If the scope(s) of the existing certificate(s) do not cover the product or processes affected, additional work and time will be required to reissue the affected certificates:

- Sufficient evidence must be reviewed to support scope change. This may require Quality System or Microbiology audits in addition to the Technical Documentation review requested.
- If in doubt, discuss the scope with the BSI Scheme Manager prior to submitting. The Scheme Manager will coordinate the scope change activities.

Subcontractors and suppliers

Are there any changes to subcontractors?

- All critical subcontractors/crucial suppliers must be added to the Unannounced Audit Visit schedule, so please ensure that your Scheme Manager and reviewer are aware of any changes. If you are unsure whether a subcontractor/supplier qualify as critical/crucial, discuss with your Scheme Manager or with the BSI Sales representative at the time of initial quotation.
- Critical subcontractors/crucial suppliers that do not hold a valid ISO 13485 certificate issued by an EU Notified Body (NB)/Conformity Assessment Body (CAB) or one of its direct subsidiaries (e.g., BSI Americas) may require a subcontractor verification audit, depending on the scope of their activities and the verification activities undertaken by the manufacturer. There may be instances where a verification audit is needed, even if they hold ISO 13485 certification from a Notified Body. Please ensure that these details are made clear in the application.

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Accessories and compatible devices

Are any devices or instruments used with the products under review? Overall, the scope of a manufacturer's activities needs to reflect their activities for the products they intend to certify. Each individual technical documentation review will be limited to the devices in the scope of the documentation and the associated device compatibility. If a Class III device, for example, requires the use of new Class IIa, Class Im or Class Is equipment that is not within the scope of the existing Quality Management System certification, additional Technical Documentation File reviews may be required for these accessories and compatible devices.

Please provide the following information for any accessories and compatible devices associated with your device:

- Brief description of the accessory/accessories including packaging configuration and how they are used with the device(s).
- Classification of the accessories and the rationale for classification.

- Technical Documentation references (file name, issue status, date).
- Evidence of compatibility with the subject devices (e.g., in accordance with Safety & Performance Requirement 14.1, 14.5 and 23.4(q) of MDR).

Novelty

Are there any new (i.e., new to manufacturer or new to medical device industry) or innovative materials, processes, assemblies or techniques associated with the devices?

- Additional consultations may be required for novel or high-risk materials, manufacturing processes, devices or indications. These may include toxicologists, statisticians, clinical users, etc.
- The EU Commission clinical evaluation consultation process, as outlined in MDR Annex IX section 5.1, will be applicable for Class III implantable devices and Class IIb active devices intended to administer or remove a medicinal product. Additional information is required for such devices during the Completeness Check process.
- Some materials (e.g., medicinal substances, human or animal tissues) may require additional regulatory consultations as outlined in MDR Annex IX section 5.2-5.4.
- BSI reviewers will still work towards timescales indicated for the review process selected, but external consultations may not fall within these timescales. Please discuss the most appropriate review option with your Scheme Manager.

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Appendix A

Information to provide in a Technical Documentation submission

Device description and specifications including variants and accessories	
Device description	
General description including product or trade names, principles of operation, mode of action etc.	Ensure that the product name, intended purpose/intended use is consistent throughout the different evidentiary documents. If not, an explanation within the main technical document should be provided, describing the differences and how they would still be applicable to the name/intended use being reviewed under MDR. The device description should enable understanding of the design, packaging, sterilisation, or other characteristics of the device. Include description, principles of operation of the device and its mode of action, key functional elements, its formulation, its composition, its functionality, whether the device is for single use only, multiple use, reprocessing and its number of cycles, sterilisation method(s) for sterile devices etc. Sufficient information should be provided to distinguish different variants of the device, and the intended purpose of different design features. For example, if one variant of a device has a coating and another does not, what is the intended purpose of that coating, and why are both variants considered to meet the requirements for safety and performance? Labelled pictures and schematics should be provided wherever possible, to enable an understanding of the device design features and intended purpose.
Accessories included	The following information should be provided for any accessories (including Class I) associated with the device: • Brief description of the accessory/accessories and how they are used with the device(s); • Classification of the accessories and rationale for classification; • Technical Documentation references (file name, issue status, date). Indicate clearly if the accessories are packaged with the device or provided separately or both. Also clarify if the accessories are already certified and if yes, provide the certificate references. Please note (as indicated in Documentation Submissions Best Practice Guide), evidence should also be provided within the Technical Documentation to demonstrate compatibility of the devices with any applicable accessories.
Accessories not included but necessary for use	The technical documentation should identify any accessories which are not included with the device, but which are necessary for its use. (E.g., identify compatibilities with instruments/implants and provide supporting evidence).

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Intended purpose and intended users	
Intended purpose including any clinical claims	The intended purpose or intended use (please refer to MDCG 2020-6 for definitions) should provide enough detail to explain the disease conditions the device is intended to treat or monitor, the basic principles of operation (i.e., intended users and environment), the intended patient population and the indications and contraindications of the device. • Indications and contraindications should be supported by objective evidence (e.g., evidence provided in the risk assessment and clinical evaluation reports). • The intended use must include 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 ensure the intended use is described consistently throughout the file (e.g., in the IFU, risk management documentation, clinical evaluation report, design requirements, Declaration of Conformity and SSCP when relevant). • If the application includes a change to the intended use, all sections of the file should be reviewed for potential impact. • For clarity it is suggested that this should be separate from the device description.
Intended users	Identify the intended users of the device (i.e., medical professionals in a speciality, clinical nurses, lay persons, etc.).
Basic UDI-DI & EMDN code	
Basic UDI-DI and any other relevant UDI related information	The Basic UDI-DI assigned by the manufacturer should be provided. Additional guidance on Basic UDI-DI may be found in the MDCG documents published on the EU Commission website. This information is to be consistent with the information on the labelling provided.
EMDN code (previously referred to as CND code)	European Medical Device Nomenclature code (EMDN code; previously referred to as CND code) should be identified (as it is required for SSCPs to be uploaded into EUDAMED).
Devices covered by technical documentation	
List of type, sizes, configurations, variants etc including catalogue numbers covered by the submitted technical documentation	A complete list of product codes should be provided, which covers the various configurations/variants of the device that are intended to be made available on the market.

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Classification	
Classification of the device including all the applicable rules and relevant rationales	Please indicate the device classification and rationale per MDR Annex VIII. The rationale should address each point of the selected classification rule. If multiple classification rules apply, all should be identified and the strictest rules resulting in the higher classification shall apply. If the device contains multiple components that on their own might be classed differently, the classification for each component should be considered in the rationale, and please note the higher classification shall apply to the device. If the device is a Well-Established Technology (WET) as per Articles 52.4 and 52.5 of MDR, a rationale supporting the determination of the device as a WET should be included considering any published guidance available on such devices. For guidance on device classification, including "borderline products" and standalone software, please refer to the MDCG documents published on the EU Commission website.
Materials	
Description and identification of key materials incorporated into the device	The technical documentation should identify the raw materials incorporated into key functional elements of the device including information on any coatings that are critical for device safety and performance. The nature of contact with the human body (e.g., direct or indirect contact, contact with circulating body fluids, etc.) should be clearly identified. Consideration should be given to agents utilised during the manufacturing processes e.g., mould release agents, cutting compounds, cleaning agents, adhesives etc. Please identify whether the device contains nanomaterials, medicinal substances, CMR/endocrine disruptors or substances that are absorbed or locally dispersed. The technical documentation should also identify the raw materials used in the packaging of the device, including primary and secondary packaging.
Identification of any tissues or cells of human or animal origin that may have been utilised in the manufacture of the device	The submission should clearly indicate whether the device utilises or is used in conjunction with any human or animal- based products or other non-viable biological substances. Materials which are or include derivatives of human or animal origin should be clearly identified.
Bill of materials	The submission should include the device Bill of Materials.

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Market history	
Overview of relevant market history of the device (e.g., Date of first making available, Units sold, Previous models, Current and previous regulatory approvals)	All submissions should be accompanied by a market history to enable an understanding of the context of device development. • If the device is new and has never been marketed by the manufacturer anywhere in the world, please state this explicitly. • For existing devices: - Ensure that a market history is provided indicating the nature and timing of any changes and that any associated documents (i.e.,, risk analyses, labelling, clinical evaluation reports, verification / validation data, etc.) account for these changes. - Provide evidence (e.g., BSI Reference numbers of previous reviews) to demonstrate that BSI has been notified of all significant changes (if applicable). - For initial applications under MDR, please confirm whether the device has been previously marketed under MDD and whether any changes have been made in comparison to the MDD-certified device. - Market history should include EU and approvals in other geographies, including sales volumes per country. - If the device is a system, ensure that the number of units sold is broken down by device component and per year. Provide Periodic Safety Update Report if applicable (see below).
Overview of previous generations and similar devices available in EU or other markets	Provide an overview of previous generations and identified similar devices available on the EU or international markets if such devices exist. This should include a comparison of these devices with the device under review to show the similarities and differences.

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Information supplied by the manufacturer

User information

Device or Product labelling	Medical devices generally use multiple levels of labelling, and it is recognised that not all devices may have the different levels of packaging specified in this section or different terms may be used than those specified here. Please provide all representative labelling which demonstrates compliance with GSPR 23 and relevant subparts. There is a requirement for the manufacturer to apply UDI carriers on the device label as per MDR Article 27(4) and depending on the classification of the medical devices as per MDR Article 123 part 3(f). Please provide justification for instances when labelling cannot be provided on the device itself.
Sterile packaging labelling	
Single unit packaging labelling	Legible and text searchable versions of all applicable levels of labels should be provided as listed above and should be representative of the finished form, showing all included symbols. Sample labels for each product configuration where there are differences in design, indications, sterilisation method etc. should be provided. It is not necessary to provide labels for every configuration if the information presented is equivalent to sample labels. If possible, provide drawings with the packaging configuration (showing placement of all labels) and label specifications.
Sales packaging labelling	The position of labels on the finished product should be clear. If the device has a sterile package, 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 harmonised standards or CS are addressed in the labels and information for use.
Transport packaging labelling	For devices which are placed on the market in bulk for inclusion in Article 22 procedure packs, information provided to the procedure pack manufacturer(s) regarding how the device should be labelled should be provided in the technical documentation to address requirements of GSPR 23.
Instructions for use/device operating manual(s)	Manufacturers must ensure that the information within the IFUs, especially related to intended purpose, indications, contra-indications, and other safety related information such as side effects, warnings is aligned with similar information from other sections such as risk management, clinical evaluation, usability, pre-clinical performance data etc. IFUs must contain all the information required as per applicable requirements specified within GSPR 23. Please provide traceability between the content of the IFU to the subparts of GSPR 23. If some subparts of GSPR 23 are considered not applicable, please provide a specific justification or rationale in the GSPR checklist. Please ensure that any specific requirements of relevant standards or CS are addressed by the IFU. Please provide surgical technique, user manual, installation and service manuals if applicable. Manufacturers must as a minimum submit the English version at the time of application. (Manufacturer's processes and procedures for translation into other languages will be audited during BSI QMS audits). For devices provided without an IFU/ Leaflet/Instructions, please provide the information detailed in GSPR 23.4(p), 23.4(v) and rationales for providing the devices without an IFU.

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Patient handbook	Some devices incorporate all the information relevant for the patient/user within the IFU itself. Some devices are accompanied by a patient handbook with additional instructions specific to the patient, for example with devices (or parts, components of the devices) that are patient operated. If the device is supplied with a patient handbook, this should be provided in the languages accepted in the Member States where the device is envisaged to be sold. The planned approach for translation of any information not in harmonised symbols should be described, if applicable.
Physicians handbook	If a separate physicians' handbook is relevant for the device, this should be provided in the languages accepted in the Member States where the device is envisaged to be sold. The planned approach for translation of any information not in harmonised symbols should be described, if applicable.
Implant card information	Please provide the implant card and information to be supplied to the patient with an implanted device, if applicable. The implant card and other information per Article 18 of MDR, and any additional information as specified in the MDCG guidance on implant cards, should be included. The device type according to MDCG guidance should be included. The location of the implant card within the device or system packaging should be clearly specified. The planned approach for translation of any information not in harmonised symbols should be described, if applicable. Aspects to consider: • Instructions for populating implant card within IFU. • Ergonomic assessment that the provided instructions are appropriate for the healthcare professional to complete the implant card correctly. • Legible, complete sample of the implant card. • Evidence for validation of lay person readability.
Language considerations	Within the technical documentation, please provide a list of EU countries in which the medical device is intended to be marketed and evidence that the national requirements of the languages used are adhered to. In the case where the marketed countries are not fully defined yet, a master template in English language is expected by BSI for initial MDR certification. After initial MDR certification, all languages should be included in the latest technical documentation. **Note:** BSI QMS auditors will review the manufacturer's processes and procedures for translation into other languages.

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Electronic IFU (e-IFU) information (if applicable, and as per (EU) 2021/2226)	If electronic IFU will be utilised, ensure compliance has been clearly outlined and evidence included to demonstrate compliance with all relevant aspects of Regulation (EU) 2021/2226. To ensure unconditional access to the eIFU and to facilitate the communication of updates, those instructions should be available on the website of the manufacturer in an official language(s) of the Union determined by the Member State in which the device is made available to the user or patient. The eIFU, if provided in addition to a paper IFU, should be consistent with the content of the IFU in paper form. Ensure evidence for compliance to the relevant parts of Regulation (EU) 2021/2226 are provided. If eIFU is being utilised in place of paper version, please demonstrate full compliance to the requirements of (EU) 2021/2226. Please submit e-labelling information as provided on the device or on a leaflet. Please provide documented risk assessment covering the elements as required by the e-labelling Regulation (this can be in the Risk Management section of the technical documentation). Please indicate if existing eIFU system has been assessed by BSI under MDR against the requirements of (EU) 2021/2226. Please provide BSI reference number (job / SMO) if available. Please identify if any changes have been made to the eIFU system since that review.
Copies of promotional materials (that mention that the device fulfils the requirements of CE marking) including any that make specific claims related to the device	Only marketing literature that mention that the device fulfils the requirements of CE marking or includes the CE mark itself is required to be provided. Supporting evidence should be provided in the relevant pre-clinical and clinical sections to substantiate any claims made in the labelling or marketing literature.
URL of the website where the IFU (and any other labelling information as relevant) will be made available as per GSPR 23.1	GSPR 23.1 requires that information related to identification, and safety and performance of the device shall be made available and kept up to date on the manufacturer's website if the manufacturer has a website. The URL of the website where such information will be made available should be included. Please explain how the requirements of Article 7 of (EU) 2021/2226 have been addressed. For devices where cybersecurity is applicable, please follow the requirements of the MDCG guidance.

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Design and manufacturing information

Design stages	
Summary of design stages applied to the device	MDR Annex II requires the manufacturer to provide "information to allow the design stages applied to the device" to be understood. Provide the design procedure. Standard operating procedures (SOPs) for design and development are not required; these typically do not apply to the specific device and will not provide understanding on the design stages of the device. Include a description of the design phases the device has gone through and the history of any major changes to the design. Provide a summary of the design process and provide linkage/traceability to supporting documentation for the current version of the device. The summary shall include an explanation and a map of previously conducted testing and outline what testing is relevant to the current version of the device. If historic testing is referenced, but a subsequent change was made and only some specifications were re-tested, please explain which test reports have been replaced and should be reviewed for each relevant specification. In addition to the above, for previously marketed or "legacy" devices certified under the Directives and applying for MDR certification, it is critical to provide the following: • Any changes in the design of the device as approved under the Directives vs. the application under MDR. • Gap analysis with current version of the design procedure.
Product and design specifications	
Key product/design specifications of the device (To include component and raw material specifications, including packaging. Specifications should include grade, quality, reference codes, full supplier details as relevant)	Overall, manufacturers should demonstrate that design requirements have been identified and documented in accordance with the intended use, safety and performance requirements, risk assessments, and relevant harmonised and other key standards or CS. The source of design requirements should be indicated. Although compliance to harmonised and other key standards is expected, please be aware that testing beyond that required by the standards may be necessary to demonstrate compliance of your device to the relevant Safety & Performance Requirements. Design requirements should be mapped to the intended use, performance and risks identified for the device. This information may be supplied in the form of a traceability matrix. Raw material specifications should be provided for key components. It is recognised that there may be some overlap and crossover between information requested in this section and other related sections. If that is the case, the manufacturer may simply point to the relevant sections of the technical documentation where this information can be found.
User requirements	Please clearly identify the user requirements for the device.

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Manufacturing information	
Overview of the Manufacturing process which also identifies any critical processes involved, including, if relevant, whether sterilisation is conducted on-site or sub-contracted	A detailed overview of the manufacturing processes should be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes. Provide a brief description of each process step, including inspections conducted at any subcontractors and the legal manufacturer. As a general principle if any of the information requested in the Manufacturing section is not available in English, the manufacturer should either provide translations or provide supplementary summary reports with translations of relevant information/sections. Or in cases where the information/reports are data heavy (or mainly graphical in nature) with very few words, the manufacturer may annotate English translations of relevant words within the reports.
Critical process verification protocols/plans **Critical process verification reports**	Please identify critical verified processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document. As a part of the initial submission, the manufacturer should include verification protocols/plans/reports for processes that are verified (as opposed to validated) and are considered critical for the safety and performance of the device. BSI reviewers may request this information for other verified processes (not originally included with the submission) during the review process if required. Justification for leveraging of verification activities with a similar device should be provided.
Critical process validation protocols/plans **Critical process validation reports**	Please identify the critical validated processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document. As a part of the initial submission, the manufacturer should include validation protocols/plans/reports for processes that are validated and are considered critical for the safety and performance of the device (e.g., coating processes, injection moulding, bonding, welding, cleaning, sterilisation, packaging, software processes etc.). BSI reviewers may request this information for other validated processes (not originally included with the submission) during the review process if required. Where a process has been the subject of a previous MDR assessment with BSI in a Master Validation Plan (i.e., validation of a process covering several devices covered by different Technical Documentations and/or dependent on different categories and/or generic groups), please provide: • Identification of the process(es) concerned. • Identification of the assessment number (SMO) and date of previous assessment report, with a satisfactory outcome. • A rationale for the proposed inclusion of the device, which is the subject of the assessment, in the validation of the process previously assessed (i.e., inclusion of the product within a defined family without challenging the worst-case scenario).
Incoming inspections and acceptance criteria & results from a sample batch	MDR Annex VII, Section 4.5.3 second indent requires that NBs examine the implementation by manufacturers of incoming, in-process and final checks and their results, as a part of technical documentation assessment.

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In-process inspections and acceptance criteria and results from a sample batch **Final inspections and acceptance criteria and results from a sample batch**	Therefore, technical documentation should include the following: • Acceptance criteria & results of incoming inspections from a sample batch for the critical raw materials and/or sub-assemblies and/or components. • Acceptance criteria & results of in-process inspections from a sample batch for the critical processes identified in sections 3.3.2 and 3.3.3 above. • Acceptance criteria & results of final inspections from a sample batch for the finished devices. • Identification of party responsible for inspection of subcontracted processes. **Note:** the same sample batch should be presented across all these inspection process steps.
Installation and commissioning tests	If the device is required to be installed and/or commissioned at the user location, please provide information on tests to be carried out as a part of the installation and commissioning of the device.
Sites involved in design and manufacturing activities	
Legal Manufacturer (as per EUDAMED registration)	The application should identify the name and location of the legal manufacturer who is placing the devices on the market. This should be consistent across the device labels and implant card (if required), IFU, Declarations of Conformity, SSCP, and technical documentation. The Single Registration Number (SRN) of the legal manufacturer should be identified. EUDAMED entries should be consistent with the information above.
European Representatives	The name and location of the EU Authorised Representative should be identified if required. Only one EU Representative should be identified, and this should be consistent across the device labels, IFU, Declarations of Conformity, SSCP, and technical documentation. The Single Registration Number (SRN) of the EU Authorised Representative should be identified.
Site with Design responsibility	The site(s) responsible for design should be clearly identified. This may be the same as the legal manufacturer or may be another internal or external subcontractor site. If a site other than the legal manufacturer is responsible for design, please provide copies of their ISO 13485 certificates (see below).
Other critical subcontractors and crucial suppliers relevant to the device(s) including copies of certification held by such entities	The name and address of any critical subcontractors or crucial suppliers (as per Commission Recommendation 2013/473/EU) should be identified, along with the service or material supplied by each. Please provide copies of critical subcontractor ISO 13485 certificates. If a critical subcontractor does not have an ISO 13485 certificate from a Notified Body with appropriate scope for the activity performed, additional supplier audits may need to be arranged (see Certificate Scope section of the main document for further information). For devices with ancillary medicinal substances, or materials of biological origin, please include relevant Quality Management certification, (e.g., EU GMP). If you have changed a supplier, please include a justification for identifying the supplier as a Critical Subcontractor, Crucial supplier, or neither, based on the guidance in MDF4102. If you remove a supplier, please provide a justification for removing them.

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General Safety and Performance Requirements (GSPRs)

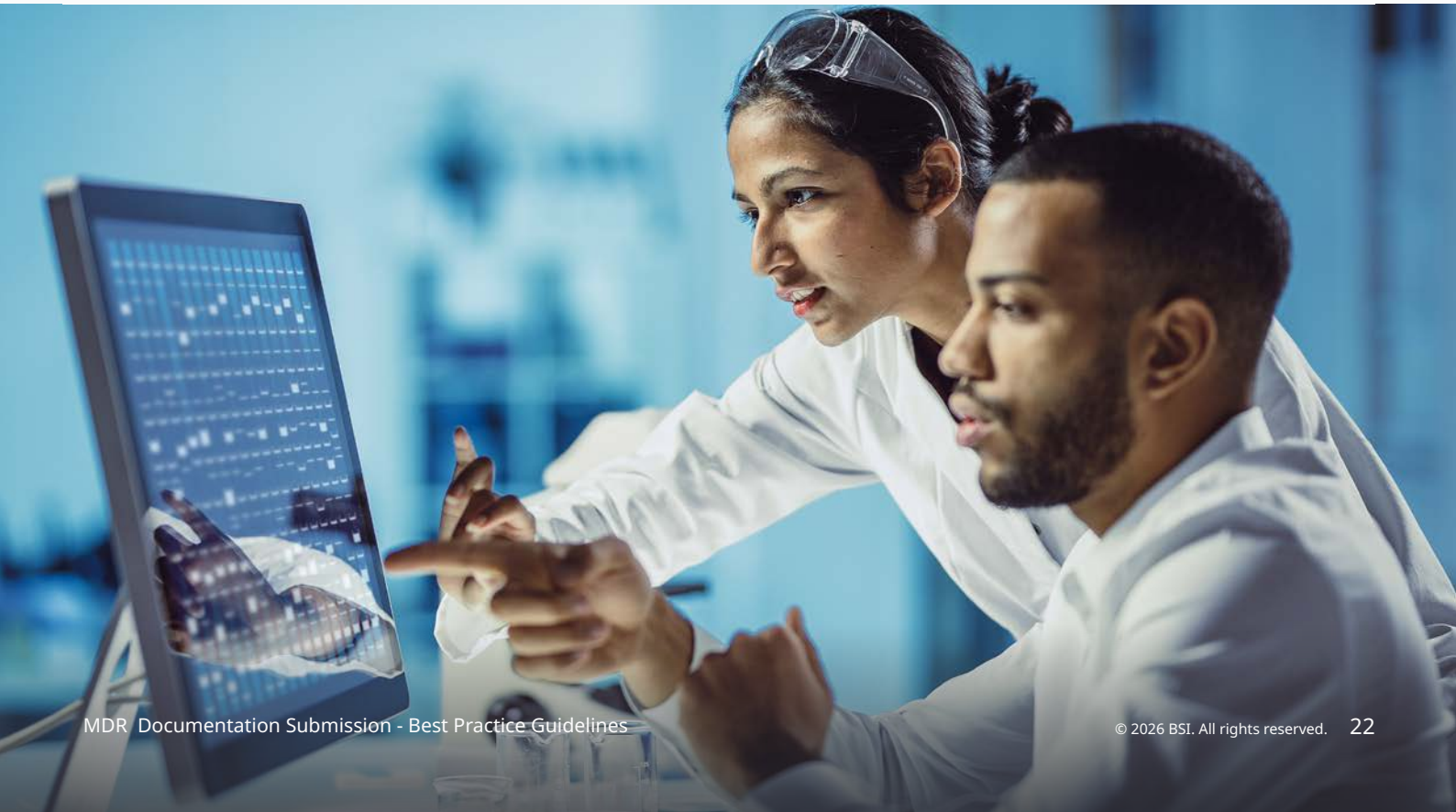
Demonstration of conformity with GSPRs

GSPR checklist (or in any other format) that meets the requirements of MDR Annex II section 4

A checklist for compliance with the applicable General Safety & Performance Requirements (GSPRs) of Annex I is important to ensure that your reviewer can locate the documentation supporting compliance with each of the GSPRs. The checklist should be approved by the responsible person (date, signature). MDR Annex II Section 4 requires the technical documentation to include a demonstration of conformity with the applicable GSPRs, including:

- The GSPRs that apply to the device and an explanation as to why others do not apply; it is not sufficient to mark GSPRs as “Not Applicable” without a justification or rationale.
- The method or methods used to demonstrate conformity with each applicable GSPR.
- Harmonised standards, Common Specifications (CS), or other solutions applied.
- The precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS, or other method applied to demonstrate conformity with the GSPR. This shall include a cross-reference to the location of that document within the full technical documentation and summary technical documentation (if applicable). The more specific the references are to documents supporting compliance, the faster the review can be conducted. For example, references to an entire section such as “Design Verification Testing” are not “precise”, and all testing may not truly be applicable to each of the GSPRs.

It is recommended that the above information is provided in the form of a checklist, or table, against the GSPRs to show how compliance with the GSPRs has been achieved.



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Standards applied including whether applied in part or full along with the version/date of the standards applied

Common Specifications applied

The documentation should demonstrate that all CS and relevant standards, both harmonised and product specific, have been considered. This is usually accomplished by means of a list of applicable standards and CS, as well as by reference to appropriate standards and CS in the appropriate documents (e.g., test reports). See Appendix B for a link to the most up to date list of harmonised standards.

- When identifying applicable standards or CS, indicate if full or partial compliance is being claimed.
- Where key standards or CS have not been applied or only partially applied, appropriate justification should be provided in the technical documentation. A summary or gap analysis regarding ability to comply with associated GSPRs (Annex I), a risk analysis and conclusion of acceptability of any compliance gaps should be provided.
- Similarly, if a more recent standard has been published where compliance is not yet claimed, confirmation of the manufacturer's awareness or ongoing gap analysis activities should be provided.
- Please indicate if there have been any changes to applicable standards or CS since the technical documentation was last reviewed by BSI. The technical documentation should continue to demonstrate that the devices meet the state of the art, including consideration of revised or replaced standards or CS.
- For legacy devices where testing and design activities may have been undertaken some time ago, manufacturers should present a gap assessment between the versions of standards applied and the most current version of those standards.

Other applicable Regulations & Directives (PPE, Machinery, e-IFU regulation etc.)

Please indicate which Regulations and/or Directives apply. If a device is governed by multiple Regulations or Directives, all applicable Regulations/ Directives should be identified. For example:

- If the device is intended to be used in accordance with both the MDR and Regulation (EU) 2016/425 (previously 89/686/EEC) for personal protective equipment, ensure that fulfilment of the relevant basic health and safety requirements of (EU) 2016/425 have been met.
- If the device is also machinery (within Article 2a of 2006/42/EC), ensure fulfilment of the relevant basic health and safety requirements of Directive 2006/42/EC Annex I have been met.
- If the devices have been impacted by subsequent Directives/Regulations (e.g., 2005/50/EC, 2003/12/EC, 722/2012, 2021/2226) ensure that these are identified, and any new requirements met.

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Benefit-risk analysis and risk management

Benefit-risk analysis	
Benefit-risk analysis (as per GSPR #1 and #8)	The risk management documentation should provide a template for preparedness, indicating whether controls (i.e., process validations, biocompatibility, sterilisation, clinical, shelf life or other key verification / validation tests) have reduced all risks as low as possible (vs. as low as reasonably practicable) to acceptable levels in light of state of the art for the device(s) under review. The assessment must demonstrate that the benefits outweigh all the residual risks when the device is used as intended. The final evaluation of Benefit-Risk shall also include the latest data from PMS. The clinical benefits of the device should be stated as per MDR Article 2 (53).
Risk management	
Risk management procedure	Please provide an overview of the risk management process and how risks are assessed, mitigated, and reduced. Please indicate whether the risk management process is based on EN ISO 14971. A thorough design and process Risk Management assessment should be conducted for the entire lifecycle of the device (from initial design concept, up to and including, device disposal). This should be updated (as appropriate) with data from PMS. The analysis must demonstrate that appropriate controls have been applied to all risks. The order of applying risk control measures should be as follows: • Inherently safe design and manufacture. • Protective measures in the medical device itself or in the manufacturing process. • Information for safety and, where appropriate, training to users. Please provide copies of the appropriate risk management documents including a copy of the risk management procedure. Please note that risk management documentation should comprise all parts/ components of a device. Risk management should be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. Special requirements of Common Specifications on Risk Management need to be included for devices covered by MDR Annex XVI. The requirements also apply in case of outsourced processes.
Risk management plan	Please provide the risk management plan associated with the device.
Risk scoring system	A copy of Risk Management Procedure(s) that include the definition of any rating systems used for risk analysis and risk acceptability should be provided. If this is part of a different document such as the risk management plan or maintained as a separate document that is specific for the subject device, then the relevant information must be included.
Design risk assessment	Please provide the documented risk assessment for the design aspects of the device. Assess whether any design changes add new hazards or reduce the likelihood of occurrence of existing hazards, irrespective of whether the risk assessment has changed. When available, please provide the Excel version of the relevant risk assessments.

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Production/process risk assessment	Please provide the documented risk assessment for the production / manufacturing process aspects of the device.
Clinical/Application/Product risk assessment	Please provide the documented risk assessment for the clinical usage/application aspects of the device. Note that for single-use devices, GSPR 23.4(p) requires the risks of re-use to be addressed in a specific section of the risk management and this should be identifiable.
Risk management report	Please provide the risk management report associated with the device, including: • The evaluation of any residual risk(s) acceptability. • Evidence that the residual risk(s) are communicated to end users. • The evaluation of the overall residual risk acceptability. • The evaluation of the benefit-risk ratio. A statement should be provided that the device, when used within the intended purpose, constitutes acceptable risks when weighed against the benefits to the patient and is compatible with a high level of protection of health and safety, considering the generally acknowledged state of the art (MDR Annex I, section 1). For MDR Annex XVI devices: a statement should be provided that the device does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the device use, which is consistent with a high level of protection for the safety and health of persons (MDR Annex I, section 9).

Product verification and validation

Biocompatibility	
Biological safety risk assessment (either stand-alone or as a part of the risk management section)	Please provide a biological safety risk assessment for the device. As specified, this may either be a stand-alone document or part of the risk management section. Where appropriate, please reference PMS data allowing the verification of device biocompatibility in the biological safety risk assessment.
Material characterisation test protocols and reports	Include all material characterisation test protocols and reports and final toxicological assessment on residuals. • For devices specified in Annex I GSPR 10.4.1 containing or incorporating carcinogenic, mutagenic, or toxic to reproduction (“CMR”) substances of category 1A or 1B (in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008), or substances having endocrine-disrupting (ED) properties, these devices must meet MDR requirements for justification of the presence of these substances above 0.1% w/w threshold. Specific labelling requirements must be met for these substances (GSPR 10.4.5). See below for further information if your device contains CMR or ED substances above 0.1% w/w in the device, components, or materials. • Where this information on CMR or endocrine-disrupting substances is provided by suppliers, manufacturers should confirm the completeness of this information and describe any additional testing or analysis performed.

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Biocompatibility test protocols and reports	The assessment should categorise the nature and duration of body contact for each component and identify any tests that are required or can be waived to establish evidence of compatibility. Justifications must be included for any tests that have been waived. • Where biocompatibility of a device is established by adoption into an existing family of devices or another biocompatibility assessment, please provide your justification on why the existing assessment is applicable to your device. For legacy devices that have been on the market before the current version of the ISO 10993 series of standards (SOTA), please provide a justification and gap analysis that supports the safety risk assessment.
Overall biological safety assessment	Biological safety assessments should be undertaken in accordance with ISO 10993-1. See Clause 7 of this standard for guidance with respect to appropriate report content for the overall biological safety assessment. Biological safety assessments should include evidence of compliance for the finished device (including consideration of all materials and all manufacturing steps). It is not enough to simply state that devices have been manufactured from materials of well-established biological safety – an assessment which considers the impact of manufacturing and sterilisation processes, intended use, packaging, storage, etc. must be provided. Biological safety assessment shall provide the manufacturer's interpretation of each of the biocompatibility tests along with the overall biological safety assessment.
CVs of the expert assessors involved in the biological safety assessment to establish competence	A justification should be provided regarding the qualifications of those involved in planning, executing, and analysing the biocompatibility assessment.

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Electrical safety and electromagnetic compatibility (EMC)	
Electrical safety test protocols **Electrical safety test reports**	Please provide the test protocols and reports for electrical safety testing, if applicable to the device. Demonstrate basic safety and essential performance for electrical safety, considering the device type and appropriate particular or collateral state of the art standards. If a subset of devices has been selected for testing and this subset is intended to represent a larger range of devices, provide supporting documentation that demonstrates how the configurations that have been tested can be considered representative of the wider set of devices/configurations. If the device is an accessory which has been covered under the testing of a system, please provide the documents related to the system. For standards to which compliance is claimed, a clause-by-clause checklist is expected to be provided. Clauses considered non-applicable must be clearly justified. When the device is designed to be used sterile, electrical testing should be performed on the sterile device. For electrical devices emitting ionising radiation, the safety of these devices in relation to these characteristics must be considered.
EMC test protocols **EMC test reports**	Please provide the test protocols and reports for EMC testing, if applicable to the device. Evidence should be provided by the manufacturer which supports requirements of basic safety and essential performance for electromagnetic compatibility in the form of a test report to state-of-the-art standards. If a subset of devices has been selected for testing and this subset is intended to represent a larger range of devices, provide supporting documentation that demonstrates how the configurations that have been tested can be considered representative of the wider set of devices/configurations. If the device is an accessory which has been covered under the testing of a system, please provide the documents related to the system. For standards to which compliance is claimed, a clause by clause checklist is expected to be provided. Clauses considered non-applicable must be clearly justified.

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Software verification and validation	
EN 62304 checklist	Appropriate documentation is required if the medical devices are either stand-alone software or rely upon software. Please provide a clause by clause checklist against the requirements of EN 62304. Copies of all documents referenced in the checklist need to be provided. If medical device is stand-alone software, guidance for the qualification and classification of the software can be found in MDCG 2019-11 and Classification guidance documents. There should be a rationale for why the software is a medical device and for its classification. If applicable, the software should be broken down into modules, some that have a medical purpose and some that do not. The modules with a medical purpose must comply with the requirements of the MDR and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices. Ensure all relevant harmonised and non-harmonised software standards have been considered. Ensure the software systems/modules/items have been assigned safety classifications based on standards. Include documentation on the medical device software life-cycle processes implemented (e.g., software design/development, maintenance/change management, risk management, configuration management, problem resolution, verification and validation processes). If software is intended to be used with mobile computing platforms, include information on specific features of mobile platforms demonstrating compliance with GSPR 17.3.
Software development plan	Include software development procedures and the software development plan (SDP) detailing the activities completed as part of the software development lifecycle (e.g., software requirements specification, software architecture, software detailed design, software unit testing procedures/reports, software integration testing procedures/reports, and software system testing procedures/reports). Documentation related to the software maintenance and software configuration management processes should also be provided (e.g., software maintenance plan, configuration management plan). **Note:** some documentation may or may not be required per the standards based on software system/module/item risk classification.
Software requirements analysis	Include the software requirements specification (SRS). An explanation regarding how the software requirements have been derived from higher level system requirements should be included and traceability to those higher-level requirements should be established. Risk controls implemented in software should also be included in the SRS. Software requirements should be clearly stated, unambiguous, and should be readily translatable into verification acceptance criteria. **Note:** see EN 62304 Clause 5.2.2 for generally expected categories that should be covered in the SRS.

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Software architectural design	Include the software architectural design (SAD). The SAD is generally represented graphically (e.g., class diagrams, block diagrams, etc.) and shows how the software requirements per section above are allocated to the SOFTWARE ITEMS that comprise the overall SOFTWARE SYSTEM. The following major areas should be addressed in the software architectural design: (1) Internal and external interfaces of the software; (2) Inclusion of any Software of Unknown Provenance (SOUP); (3) Segregation measures that may be necessary for risk control purposes. A documented SOUP list in tabular form should be submitted, this includes libraries, that clearly indicates: The Name, The Version, The Manufacturer of the SOUP, the functional and performance requirements for the SOUP, or reference to said requirements, where applicable.
Software detailed design	For EN 62304 Software Safety Class 'B' and 'C' software, include the software detailed design (SDD). The SDD represents a further refinement of the software architecture described in the section above. The SDD should clearly identify the SOFTWARE UNITS that are derived from the SOFTWARE ITEMS specified in the software architecture. The SDD should provide details regarding the function and expected inputs and outputs of the SOFTWARE UNITS. In general, the SDD should provide enough detail to allow correct implementation of the SOFTWARE UNITS and their expected interfaces.
Software unit implementation and verification	For EN 62304 Software Safety Class 'B' and 'C' software, include evidence of SOFTWARE UNIT verification. These may include unit test protocols/scripts and associated reports. Note that this type of testing is usually considered "white box" testing in that detailed knowledge of the underlying software code is usually required to properly design the unit verification tests. Where automated testing has been used to perform verification activities, include the test scripts and the test log results in the submission documentation.
Software integration and integration testing	For EN 62304 Software Safety Class 'B' and 'C' software, include evidence that software integration testing has been performed. Please note that this testing should be aimed at showing how the SOFTWARE ITEMS (which are internal to the SOFTWARE SYSTEM) function as expected when integrated together. Areas to investigate can include, for example, expected timing, functioning of internal and external interfaces, and testing under abnormal conditions/foreseeable misuse. This testing is typically not conducted on the final, compiled code and will normally make use of a test/simulation environment where various combinations of SOFTWARE ITEMS can be tested in isolation. It is permissible to combine software integration testing with software system testing (per section below). Where this strategy has been employed to cover the requirement to perform software integration testing, this should be clearly explained in the submission documentation. Where automated testing has been used to perform verification activities, include the test scripts and the test log results in the submission documentation.

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Software systems testing	Include the software system test protocol(s) and report(s). This testing should demonstrate that each of the software requirements (per software requirements analysis section above) have been verified. It is expected that traceability between the software requirements and the software test cases/test procedures should be established. This testing is typically conducted on the final, compiled SOFTWARE SYSTEM. Input stimuli, expected outcomes, pass/fail criteria, and test procedures should be clearly established in the test documentation. Where test failures or deviations have been encountered, these should be clearly documented and justified in the provided reports. Where automated testing has been used to perform verification activities, include the test scripts and the test log results in the submission documentation.
Software release	Include the list of known residual anomalies. The following information on each remaining anomaly should be included: • Unique Identifier. • Brief description of the issue. • Severity/Risk Level. • Justification for why it is acceptable to release the software with the anomaly. Also include documentation showing how the released software was created (e.g., procedure and environment used to create the released software). The final released software version number should be identified in this documentation. Documentation explaining how the released software is archived and how it can be reliably delivered (e.g., to the manufacturing environment or to the user of the software) should be included.
Software risk assessment	Include software risk assessment documentation (e.g., software hazard analysis, software failure mode and effects analysis, fault tree analysis, traceability etc.). **Note:** some documentation may or may not be required per the standards based on software system/module/item risk classification.
Cybersecurity documentation	Include documentation related to the design and maintenance of the cybersecurity features of the medical device. Documentation should include: • Threats and the associated protections needed to ensure the **confidentiality**, **integrity** and **availability** of the data. • The security risk management plan, security risk assessment and verification/validation evidence for the identified security risk controls. • Security capabilities and security controls captured in requirements. • Minimum IT requirements. • Security verification and validation documents. • Documentation showing how cybersecurity threats are monitored and responded to as part of the post-market surveillance. **Note**: see MDCG 2019-16 Guidance on Cybersecurity for medical devices.

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Stability, including shelf life	
Stability/shelf-life validation protocols (to include both device and packaging performance) **Stability/shelf-life validation results and reports**	Shelf Life Validation should include the following for the device and packaging: • Protocol (with acceptance criteria for each test performed) and appropriate test methods or reference to standards utilised; • A clear statement of the intended shelf life. • A clear statement defining the sterilisation status of the test samples (1X, 2X sterilised). • A summary of the accelerated aging parameters (time, temperature, and humidity) and how the aging times were calculated. • Real Time Aging protocol and a statement on progress if studies are still on-going. • A clear justification of statistically significant sample size. • Individual test data protocols and reports supporting the package stability at the claimed shelf-life (seal integrity, seal strength etc.) • Individual test data protocols and reports supporting the device stability at the claimed shelf-life (functional testing, chemical/analytical etc.) • A summary of any ship testing/transit simulation testing conducted and applicable test protocols and reports (refer to Packaging and Transit Testing section below in the document). **Changes:** • Extensions/changes to shelf life for Class III devices and Class IIb implantable devices (non-WET) must be reported to BSI for review and certificate re-issue. • Provide the technical documentation to support the change in the claimed shelf life for the device and/or packaging. Provide linkage to previous, related submissions (BSI ref. number). For devices which are provided in bulk to be placed on the market within Article 22 procedure packs, documentation supporting shelf life of the bulk component prior to use in the pack should be provided, as well as information provided by the Original Equipment Manufacturer (OEM) to the procedure pack manufacturer regarding shelf life. **Note:** • Shelf life is normally considered to be the time the device can be kept in the packaging prior to its first use. This is not the same as “Lifetime”. • Shelf-life testing is not restricted to the packaging. The device itself should be subject to shelf life testing, or a rationale provided to demonstrate why its characteristics are not expected to degrade over the claimed shelf life. • If shelf life claim is based on accelerated age testing, provide the protocol for real time testing. Real time study should be underway by the time documentation is submitted for review. • Impact to shelf life should be considered when changes are made to the device, packaging, or critical manufacturing steps / processes. • It is not necessary to provide all previous shelf-life protocols and reports. Provide only the protocols and reports applicable to the current version of the subject device.

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Performance and safety – design verification and validations	
Design control matrix	A design verification/validation strategy document and/or summary of the outcomes should be provided. Verification/validation results should be provided for each design requirement. If compliance has been demonstrated without testing, an appropriate rationale should be provided. For previously marketed or "legacy" devices applying for MDR certification, it is critical to provide an explanation and map of previously conducted testing and outline what testing is relevant to the current version of the device. If historic testing is referenced but a subsequent change was made and only some specifications were re-tested, please explain what test reports have superseded and should be reviewed for each relevant specification. If multiple test reports are provided, it is important to clearly identify which variants of devices the reports apply to, and which reports are the intended most recent report for each tested specification.
Design requirements	Please provide the documented design requirements for the device.
Verification and validation plan	Please provide an overall plan for design verification and validation, if applicable.

Verification protocols and results	Test reports should document objectives, acceptance criteria, materials & methods, results, protocol deviations and conclusions.
	
	If test results are considered representative for a group of devices (i.e., worst-case devices or comparative devices), then a justification for leveraging protocol(s) and report(s) should be provided for the subject devices under review.
	
	Similarly, if testing has been undertaken on prototypes, previous generations of a device, or devices that otherwise do not represent the finished goods, a justification for the adequacy of this testing should be provided.
	
	If multiple design verification/validation studies were conducted, please provide a flow chart or table that shows how the studies were conducted and highlight which study ultimately demonstrates that the design meets the product performance specifications. Please include compatibility studies for the subject device (e.g., verification with instruments, with other implants etc.)
	
	For line extensions or devices based on "existing" devices, it may be possible to leverage data from testing undertaken on the existing devices. In this case, a rationale for the use of existing data must be provided, including:
	
	• Detailed comparison to the comparative devices – a table showing the similarities and differences greatly speeds up the review process. Key things to consider include (but may not be limited to):
	  • Materials of construction.
	  • Indications for use.
	  • Methods of manufacturing.
	  • Key design features.
	• An evaluation of the impact of any differences on clinical safety, performance and testing undertaken. The evaluation should support the conclusion that the new devices do not represent a worst case in terms of testing, when compared to the devices previously tested.

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Validation protocols and results	Please provide the protocols and results for design validation studies. See also previous section for guidance on appropriate contents and rationales. Design validation should be directly linked to customer/user needs and will generally take the form of a user study, clinical data or market history.
Usability study protocols and results	Summarise any usability assessments in compliance with EN 62366 or other applicable standards. The approach to usability assessment should be in line with the intended users and intended use. Please provide the protocols and results for usability studies. See also previous sections for guidance on appropriate contents and rationales.
Evidence to support the device lifetime in use	The lifetime of the device must be clearly stated and defined as well as considered relative to other parts of the technical documentation (e.g., risk management, clinical evaluation, PMS). Product lifetime is normally considered as the time from first use until the device ceases to fulfil its intended use. This is not the same as "Shelf Life". • Per GSPR 6 the lifetime should be supported for the stresses occurring during normal conditions of use and when the device has been properly maintained in accordance with manufacturer's instructions (if applicable). • The manufacturer should clearly identify how each element of total device lifetime has been verified and provide supporting evidence. • For implants, ensure that consideration is given to functional use of device versus total implant life.
Sample Size Procedures	Please clearly define how sample sizes have been determined and the rationale/ justification for the sample sizes. If the rationale is documented in a procedure, please provide the relevant procedure.
Clinical Evaluation	
Clinical development strategy	Please explain the clinical development strategy for the device. Where an opinion has been provided by the expert panels on the clinical strategy of the device(s) per MDR Article 61 (2), please provide a copy of the opinion and reference. Please state whether the device is considered an 'Orphan Device' in line with the definition provided in MDCG 2024-10. Where an opinion has been provided by the expert panels on the status and qualification of the device as an 'orphan device' please provide a copy of the opinion and reference.
Clinical development plan	See MDR Annex XIV, Part A, 1 (a) final indent. For legacy devices (and if applicable) please provide a justification within the clinical development plan for any deficiencies as described in the final indent noting any reference to PMCF activities that are ongoing or reference to the PMCF Plan as described in Annex XIV. The clinical development plan should be part of the Clinical Evaluation Plan.
Clinical evaluation plan	Please provide the clinical evaluation plan documented and used for the device. See MDR Annex XIV, Part A, 1 (a). **Note:** a legacy device may have a clinical evaluation plan that is different to a new device under MDR. MDCG 2020-6 Appendix II describes the expected content of a legacy device clinical evaluation plan. Legacy devices are still required to have a clinical development plan per MDR Annex XIV Part A.

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Clinical evaluation report	A Clinical Evaluation Report is always required for a medical device per MDR Article 61 (12). Representative clinical data must be provided for all indications and variants. Clinical data is also needed to support intended use and contraindications (as previously noted in this document) as well as patient population, users, lifetime, claims and clinical benefits, variants and/or size ranges. The clinical evaluation should include all available data relevant to supporting safety and performance of the device. The clinical evaluation report should be a standalone document, which should specify the frequency of report updates and provision of this rationale. Justifications for why one group of data is representative of another must be clearly substantiated. If clinical data is obtained from scientific literature, provide detailed description of the search criteria, literature exclusion/inclusion criteria, appraisal methods, and analysis of the data. If no clinical investigation data are available for the subject device and the Clinical Evaluation relies on a justification of equivalence of comparative devices, the justification must identify and discuss the potential clinical impact of all differences between the subject and comparable devices relative to intended use, technical, or biological factors (Refer to MDR Annex XIV Sec. 3 and MDCG 2020-5/MDCG 2023-7). In the context of equivalence, manufacturers should also include any additional information necessary to show compliance with the requirements of MDR Article 61.5 for implantable devices and Class III devices. If the device is a system, or part of a system, with multiple components the clinical evaluation must consider all the components of the device. The clinical evaluation must give due consideration to the accessories associated with the device and/or compatibility with other devices.
CVs of the relevant personnel associated with the Clinical evaluation report to establish appropriate competence	A justification should be provided (with appropriate evidence) to substantiate the qualifications of individual(s) conducting/approving the clinical evaluation. Ensure that CVs and Declarations of Interest are appropriate for the device under evaluation (e.g., including an end user of the device, e.g., medical professional).
Clinical investigation protocols	For any devices without suitable equivalents and / or insufficient data in the literature, pre-market clinical investigation may be required. In addition, for Class III devices and Class IIb implantable devices, pre-market clinical investigation will be required unless: • The device is demonstrated to be equivalent to another of the manufacturer's own devices with sufficient clinical data available demonstrating conformity with the relevant GSPRs. • The device is demonstrated to be equivalent to an already marketed device of another manufacturer and a contract is in place explicitly allowing ongoing access to that manufacturer's technical documentation. • For listed device types where the clinical evaluation is based on sufficient data and in compliance with relevant CS. • The device had been lawfully placed on the market or put into service per Directives 90/385/EEC or 93/42/EEC and CE mark is valid, where the clinical evaluation is based on sufficient clinical data and is in compliance with any relevant CS.

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Clinical investigation protocols - *continued*	• Annex XIV and XV describe Clinical Evaluation and Clinical Investigations, respectively. Guidance is also available in EN-ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice. If a pre-market clinical investigation has been conducted, please ensure: • All appropriate documentation (CIP, letter of "no objection" from the Competent Authority, evidence of Ethics approval, final report, etc.) is provided. • The final clinical trial protocol agrees with that submitted to the Competent Authority, and evidence that any deviations have been agreed with the CA has been provided. • The final report demonstrates that requirements for all safety and performance endpoints have been met. • There are no open clinical investigations relevant to your devices with endpoints related to safety or performance claims.
Clinical investigation results	• If a pre-market clinical investigation has been conducted, please ensure: • The final report demonstrates that requirements for all safety and performance endpoints have been met. • There are no open clinical investigations relevant to your devices with endpoints related to safety or performance claims. See also previous section.
Statistical analysis plans	A clear description must be provided of the statistical tools, techniques, analyses used in the design and conduct of clinical investigations, and analysis of clinical data within the overall clinical evaluation.
Copies of literature articles	A copy of all literature articles selected and analysed within the clinical evaluation report should be available and may be requested during the technical documentation assessment.
Summary of Safety and Clinical Performance	For Class III and implantable devices excluding custom-made or investigational devices, a Summary of Safety & Clinical Performance (SSCP) per Article 32 must be provided in the technical documentation. • The SSCP should be written clearly and understandable to the intended user and patient (if relevant) and should contain all the elements listed in MDR Article 32, Section 2. • Please consult current available guidance for SSCP content and format as per MDCG 2019-9. • Where patient information is relevant to the SSCP, the information for the intended user and the information for patients should be presented in two separate parts within a single SSCP document. If a patient section is not considered to be necessary, a justification is required. • Ensure the SSCP layout template and guidance provided for the layperson in MDCG 2019-9 is applied and the provided example statements have been considered. Please provide evidence of an appropriate validation technique of the layperson test for SSCP content. • Ensure that the SSCP content aligns with the scope of the review. Where an SSCP covers multiple devices, ensure that the devices are all covered under the scope of the review.

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Summary of Safety and Clinical Performance
- continued

- It is acceptable to provide a draft version of the SSCP at the time of the initial submission. Once the content has been checked and the adequacy of the clinical data confirmed by BSI, a final copy of the SSCP with a completed revision history should be submitted. The final SSCP should be in English and in a pdf format which is printable and searchable. BSI is responsible for uploading the final validated, English version of the SSCP to EUDAMED.
- The manufacturer is responsible for updating the SSCP. As outlined in Article 61(11) the SSCP should be reviewed and, if indicated, updated at least annually. If the manufacturer's annual review confirms that the clinical and safety information in the SSCP remains correct, complete and aligned with the technical documentation, there is no need for the manufacturer to update or reissue the SSCP.

SSCPs covered under quality assurance certificates:

For Class IIa implantable and Class IIb implantable WET (Well-Established Technologies) devices, MDR allows NBs to choose representative devices from each device category or generic device group respectively for the assessment of technical documentation. The SSCPs for such devices chosen as the representative samples will be validated by the NB as part of the technical documentation assessment for those devices. SSCPs not validated during the initial conformity assessment will be validated when the relevant technical documentation is assessed for surveillance purposes as per the manufacturer's sampling plan.

As BSI does not upload unvalidated SSCPs to EUDAMED, unvalidated SSCPs should be held and maintained by the manufacturer. Unvalidated SSCPs do not need to be submitted to BSI.

SSCP language requirements:

The MDCG guidance on SSCPs, MDCG 2019-9, also includes several requirements related to languages, translations of SSCPs depending on the Member State requirements related to languages and the availability of translated SSCPs on EUDAMED prior to placing affected devices on the market within these Member States. Manufacturer's processes/procedures related to making the translated SSCPs available to BSI (for the NB to upload these to EUDAMED) and ensuring that they are available on EUDAMED prior to placing the devices on the market within these Member States will be audited as part of the BSI QMS audits).

As BSI only validates the English SSCP and is not uploading translations of SSCPs to EUDAMED, the manufacturer should not submit translations of the SSCP to BSI.

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Post Market Surveillance & Post Market Clinical Follow-up	
Post Market Surveillance data (Market History, worldwide and EU sales volumes, Complaints data and trend analyses; Vigilance data and trend analyses; data from other PMS sources)	Please provide sales, complaints, and vigilance data for the last 5 years for your device: • Sales and complaints data should include sales outside of the EU. A breakdown should be provided to enable evaluation of sales and complaints by region. • Complaints data should be evaluated rather than just listed. For example: - Why is the complaints rate considered acceptable? - Have any trends been analysed and noted, or corrective actions taken? - What is the status of these actions? - Has a comparison of PMS data been made to the expected occurrence in the risk assessment? - Full details of vigilance issues should be provided, including the status of any Field Safety Corrective Actions or Notices, the associated CAPAs and patient outcomes. This data should include FSCA or FSN outside the EU, if related to a device which is sold in the EU. • Ensure that the PMS data submitted at the time of the submission is as current as possible. • For other PMS sources, please reference real world evidence sources such as electronic health or medical records, databases capturing details of procedures, (e.g., insurance/reimbursement).
Post Market Surveillance Plan	A Post-Market Surveillance Plan (PMS Plan) commensurate with the product risk, lifetime and available clinical data should be provided for each device / device family, as per MDR Article 84. • The PMS Plan should cover all the elements as specified in MDR Annex III and MDCG guidance on the PMS system. • Ensure that the PMS plan adequately justifies the monitoring of the safety and intended performance of the device. • Post-Market Clinical Follow-up (PMCF) is required under the MDR, but if an adequate justification is provided based on the risk and clinical data available for the device, then PMCF will not be part of the PMS Plan. • A copy of the Post Market Surveillance procedure should also be provided. Please note that the procedure is not the same as the Plan – the former refers to the manufacturer's quality system requirements and is generic to all devices marketed by a manufacturer, whereas the latter is specific to the subject device, and can only be generated considering data from the clinical evaluation and risk evaluation for that device.
Periodic Safety Update Reports (if available)	For Class III, IIb, and IIa devices, manufacturers must prepare a periodic safety update report ("PSUR") for each device or group of devices summarising results and conclusions of post-market surveillance data analysis as a result of the PMS plan described above. The PSUR should contain all the elements outlined in MDR Article 86 and any applicable MDCG guidance documents, including MDCG 2022-21. Any PSURs the manufacturers may have issued by the time of submission must be included.

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Post market clinical follow-up plan & protocols	Please provide a detailed PMCF plan including all necessary elements outlined per Part B of MDR Annex XIV and any applicable MDCG guidance documents. If the PMCF plan includes a PMCF study, include the study protocol.
Post market clinical follow-up reports	Include any information and reports from PMCF activities previously carried out. This should clearly identify the PMCF study, which products are included and the applicable indication of use. In cases with multiple products and studies a table is preferable. The Notified Body may be required to periodically review results from ongoing or completed PMCF studies following CE mark certification, including a specialised clinical evaluator in some cases.
Devices incorporating medicinal substances	
Overview (Module 1) **Medicinal substance: Copy of signed CEP or ASMF/PMF and letter of access or CTD 3.2.S dossier section**	The Medicinal dossier provided should comply to MEDDEV 2.1/3 and follow CTD headings in a bookmarked format. The Medicinal dossier will be a standalone dossier to the technical documentation as it will be sent to a Competent Authority for further assessment. Further guidance on the dossier structure can be found **here**.
Device: CTD 3.2.P Module 3 including development, manufacture, intermediate and end product specifications and tests, and stability. **Module 4: Non-clinical data relating to the medicinal substance and device** **Module 5: Clinical data relating to the safety and efficacy of the medicinal substance** **Device IFU and labelling**	The submission should clearly indicate whether the device utilises, or is used in conjunction with, any medicinal substances or substances absorbed by or locally dispersed in the human body. If the device is a system and includes multiple components, then identify the components which incorporate these medicinal substances. Devices which incorporate medicinal substances or substances absorbed or locally dispersed may be subject to requirements of additional European Directives / Regulations. Additional review resources may be required, including external independent reviewers and/or Competent Authority consultation and/or a European Agency for the Evaluation of Medicinal Products (EMA). Some EU Competent Authorities require that the IFU and labels are included in the CTD format Medicinal dossier that is submitted to them for carrying out the consultation process. Please include a copy of the device labels and IFU within the Medicinal dossier.

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Devices utilising tissue and cells of human or animal origin or their derivatives or other non-viable biological substances (as per GSPR 13.3)

Information on the nature of the starting materials, species, and geographical source

Animal/Human tissue (or their derivatives) related risk assessment (either stand-alone or as a part of the risk management section)

The submission should clearly indicate whether device manufacture utilises any human- or animal-derived substances or other non-viable biological substances. If the device is a system and includes multiple components, then identify the individual components which utilise or incorporate these substances.

Manufacturing subcontractors should be consulted if appropriate to establish if any such substances are used during manufacture, even if they do not feature in the final device (e.g., lubricants or mould release agents which may use animal-derived substances). The manufacturer should request evidence of compliance to ISO 22442 or EU 722/2012 for any applicable exclusions (e.g., for tallow derivatives, species and processing method utilised) from the subcontractor. If in doubt, speak with your Scheme Manager before submitting technical documentation.

Devices which incorporate human or animal-derived substances may be subject to requirements of additional European Directives/Regulations. Additional review resources may be required, including external independent reviewers and/or Competent Authority consultation.

The submission should include representative labelling which demonstrates compliance with the relevant subparts of GSPR 23 for devices incorporating human- or animal-derived substances.

Justification for the use of animal/human tissues or their derivatives

For devices utilising materials of human origin (GSPR 13.1), documentation submitted shall include:

- Benefit-risk assessment reflecting all hazards associated with use of the materials of human origin.
- Justification with clearly identified clinical benefits that support utilisation of the material of human origin in the device versus other lower-risk available alternatives (e.g., synthetic or animal-derived) for the intended purpose.
- Donation, procurement, and testing as per Directive 2004/23/EC, including nature of the starting materials and evidence relating to non-viability.
- Processing, preservation, and handling methods, including sourcing and manufacturing procedures, used to ensure safety to patients, users, and others by minimizing risks related to transmissible agents.
- Traceability system compatible with requirements per Directive 2004/23/EC and Directive 2002/98/EC.

Information to establish compliance with EN ISO 22442-1 (for materials of animal origin)

- **Requirements of EN ISO 22442-1:**
  - Benefit-risk assessment reflecting all hazards associated with use of the materials of animal origin. For devices under the scope of 722/2012, this should also include a rationale for the acceptability of the overall TSE risk with an estimate of the TSE risk arising from the use of the product, considering the likelihood of contamination of the product, the nature and duration of patient exposure, and any measures used to inactivate TSE. Zoonosis status is to be provided.
  - Justification supporting utilisation of the material of animal origin (including the species and tissue selected) considering the balance of residual risk and medical benefit as compared to other lower-risk available alternatives (e.g., synthetic or lower-risk species) for the intended purpose. For devices under the scope of 722/2012, there must be clearly identified clinical benefits that support utilisation of the material of animal origin in the device versus other lower-risk available alternatives for the intended purpose.

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Information to establish compliance with EN ISO 22442-2 (for materials of animal origin)	• **Requirements of EN ISO 22442-2:** - Names and addresses of all establishments in the animal tissue supply chain, and applicable certification (e.g., ISO 13485, food safety, etc.) - The nature of the processing that takes place at each facility. - The technical agreement between the manufacturer and the supplier of the animal tissue with material specifications. - Procedures and process controls to prevent cross contamination between species and higher infectivity tissues. - Provide sample of batch records including evidence of inspection at abattoir and incoming inspection for animal tissue at manufacturer. - System for traceability in the animal tissue supply chain with pooling limit considerations. - Manufacturer's audit plan and latest audit report for each supplier. - For devices under the scope of 722/2012, a valid EDQM certificate, if available.
Information to establish compliance with EN ISO 22442-3 (for materials of animal origin)	• **Requirements of EN ISO 22442-3:** - Identification of validated inactivation / elimination steps in the manufacturing process for viruses and TSE. - Literature review protocol and report for viruses/TSE inactivation. - Inactivation study protocol and report for viruses/TSE.
Evidence to support compliance with GSPR 13.3 for devices utilising non-viable biological substances	For devices utilising non-viable biological substances (GSPR 13.3), documentation submitted shall include: • Names and addresses of all establishments in the substance supply chain. • Risk assessment reflecting all hazards associated with use of the non-viable biological substance. Processing, preservation, testing, and handling methods, including sourcing and manufacturing procedures, used to ensure safety to patients, users, and others by minimizing risks related to transmissible agents.
Devices composed of substances that are absorbed by or locally dispersed in the human body (Rule 21 devices)	
Test protocols/reports and data for detemining the absorption, distribution, metabolism, excretion of those substances **Test protocols for determining Test protocols/reports for determining the local tolerance of those susbtances** **Test protocols/reports for determining the possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances** **Test protocols/reports for determining the toxicity of those substances**	GSPR 12.2 requires that for devices that are composed of substances that are absorbed by or locally dispersed in the human body (as per Rule 21 of MDR Annex VIII) manufacturers consider the relevant requirements of Directive 2001/83/EC in relation to absorption, distribution, metabolism, excretion (commonly referred to as ADME profile), local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions. Information and/or test data related to these requirements should be included in the technical documentation. If evidence is based on published literature, manufacturers should rationalise the applicability of such literature data to their own device considering the nature of their device, intended purpose, contact with various body tissues and other substances etc. If the manufacturer has determined the substances are not absorbed, evidence should be provided rather than stating Not Applicable to the requirements of the GSPR.

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Devices containing CMR or endocrine-disrupting substances referred to in GSPR 10.4.1 of Annex I of MDR	
Data related to the estimation of potential patient or user exposure to the substances **Information/data on analysis of possible alternative substances, materials or designs** **Rationale for the presence of CMR and/or endocrine-disrupting substances above 0.1% (w/w) considering the alternatives** **Labelling indicating the presence of CMR and/or endocrine-disrupting substances above 0.1% (w/w)**	GSPRs 10.4.1 - 10.4.5 describe specific requirements for some types of devices that contain substances which are carcinogenic, mutagenic, or toxic to reproduction and substances having endocrine-disrupting properties above 0.1% (w/w) threshold. Information and/or test data related to these requirements should be included in the technical documentation. This information may be provided either as a stand-alone section or incorporated into other relevant sections such as biocompatibility, labelling etc. It is best practice to ensure the information on analysis and rationales for any CMR and ED is clearly identifiable in the technical documentation. Analysis of possible alternative substances, materials, and designs should include an explanation of the methodology used to identify alternatives. Guidelines from the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) should be considered. If evidence is based on published literature, manufacturers should rationalise the applicability of such literature data to their own device considering the nature of their device, intended purpose, contact with various body tissues and other substances etc. Labels should clearly identify presence of CMR or ED which are present above 0.1% (w/w). Consideration of vulnerable patient populations must be made per GSPR 10.4.5, and this information should align between the IFU, CMR-ED justifications, and other technical documentation.
Packaging and transit (transport) testing	
Packaging drawings and/or configurations	A complete packaging BoM and diagrams including specifications and suppliers should be provided to illustrate how each device is packaged. For devices which are placed on the market in bulk to be included in Article 22 procedure packs, any information provided by the OEM to the procedure packer regarding compatibility of the packaging materials and components should be included in the technical documentation.
Packaging validation protocols **Packaging validation reports**	Please provide the protocols and reports for packaging validation. For sterile devices, this must include the validations carried out towards establishing the sterile barrier. Provide evidence of validation for package integrity test methods utilised. For non-sterile devices, evidence should be provided to establish that the packaging sufficiently protects the device in order to enable it to achieve its intended performance. • Packaging testing needs to be undertaken in accordance with relevant standards. If such standards are not used, alternate methods must be duly justified in terms of their suitability and state of the art. • If all packaging configurations / device combinations have not been tested, a rationale based on worst case (i.e., heaviest and lightest devices, sharp or pointy edges, etc.) should be provided. • Changes to packaging could potentially be considered as significant changes. For Class III devices and Class IIb implantable devices, these must be reported to BSI for review and certificate re-issue.

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Transit/transport testing protocols

Transit/transport testing reports

Please provide protocols and reports for transit/transportation testing conducted on the device to establish transit endurance and maintenance of the sterile barrier in case of sterile devices.

Transit/Transport Testing should include the following for the device and packaging:

- Protocol (with acceptance criteria for each test performed) and appropriate test methods or reference to standards utilised.
- A clear statement of the considered transit modalities (air, rail, road, etc.)
- A clear statement defining the sterilisation status of the test samples (1X, 2X sterilised).
- A summary of the environmental/climatic conditioning parameters.
- A clear justification for a statistically significant sample size.
- Individual test data protocols and reports.
- For changes impacting Class III devices and Class IIb implantable (non-WET) must be reported to BSI for review and certificate reissue.

For devices which are placed on the market in bulk to be included in Article 22 procedure packs, protocols and reports should be provided to demonstrate that transportation of bulk components does not damage the product or render it unusable in transportation to the procedure packer. Once components are placed into a procedure pack, requirements outlined above for the device and its packaging are also applicable.

Sterilisation

Sterilisation Validation protocol

Sterilisation Validation results and reports

Sterilisation validation information must be provided as part of the technical documentation submission for sterile devices and end-user sterilised devices.

- Documents should describe:
  - Use of “State of the art” process validation methods.
  - The bioburden test method validation and data.
  - The product qualification (Dose verification, BI suitability testing, SAL calculations).
  - The process qualification (Performance qualification, Dose Map, BI Inactivations).
- Appropriate rationales are required if sterilisation validation is by adoption into an existing family or sterilisation validation.
- Devices for End-User-Sterilisation also require review of cleaning, disinfection, and sterilisation validation / adoption with respect to parameters recommended in the IFU.
- Manufacturers should include information on testing and control of bacterial endotoxins (pyrogens) on their devices.
- Summary documentation/reports should provide an audit trail to the raw data.

Additional guidance relating to specific document types is provided below.

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Sterilisation Validation protocol

Sterilisation Validation results and reports

- continued

Sterilisation Validation – Radiation should include:

- Protocol.
- Justification for selection of product/master product / worst-case representative product.
- Dosimetry mapping data (typically from the sterilisation contractor) Validation of bioburden testing method and test report.
- Bioburden determination and test reports.
- Calculation or determination of verification dose and full dose.
- Validation of product sterility testing method & test report.
- Sterility testing of verification dose samples & test report.
- Overall report.

Sterilisation Validation – Ethylene Oxide should include:

- Protocol.
- Justification for selection of product / master product / worst-case representative product.
- Summaries regarding commissioning of the sterilisation equipment.
- Validation of bioburden testing method & test report.
- Bioburden determination and test reports.
- Biological indicator data.
- All cycle data and test reports (fractional, half, full).
- Validation of product sterility testing method & test report.
- Product sterility testing & test report.
- Sterilant residual analysis reports.
- Overall report.

Sterilisation validation is reviewed separately by a BSI Microbiology Specialist

For devices which are placed on the market in bulk for inclusion within Article 22 procedure packs, sterilisation instructions provided to the procedure pack manufacturer(s) should be provided in the technical documentation. Validation of the sterilisation methods should also be provided.

Handling Multiple Routes of Sterilisation and/or Equipment

- Validation documentation should include records relating to all sterilisation locations.
- Documentation should demonstrate completion of validation activities at all locations for all equipment.
- Validation records shall be traceable to the devices under review.

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Reusable devices (including surgical instruments)	
Cleaning, Disinfection, Sterilisation Validation Protocols/ Reports in support of the instructions within IFU	**End User Sterilisation Product documentation should include:** • Instructions for use that detail the validated cleaning, disinfection, and sterilisation parameters. Please be aware that reference to "standard hospital practice" is insufficient. • Validation protocol and report for the sterilisation parameters listed in the IFU. • Validation protocol and report for the disinfection parameters listed in the IFU. • Validation protocol and report for the cleaning parameters listing in the IFU. • For reusable devices which are placed on the market in bulk for inclusion within Article 22 procedure packs, cleaning, disinfection, and sterilisation instructions provided to the procedure pack manufacturer(s) should be provided in the technical documentation. Validation of the cleaning, disinfection, and sterilisation methods should also be provided.
Devices with a measuring or diagnostic function	
Protocols/Reports for tests associated with establishing the device limits of accuracy, precision, calibration etc.	If the device has a measuring function or diagnostic function, include test protocols and reports used for verifying or establishing the device limits of accuracy, calibration, precision, and stability etc. Refer to MDCG 2021-24 for guidance on criteria that qualify a device as having a measuring function.
Devices intended to be operated together with other devices to operate as intended	
Protocols/Reports for tests associated with establishing the safety and performance of the device and the combination while connected to other devices and their interoperability	If the device is intended to be operated together with other devices or products to operate as intended as per GSPR 14, include test protocols and reports that establish the safety and performance of the combination of devices including addressing their interoperability and any usability elements.

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Magnetic resonance imaging safety of implants	
MRI safety test protocol **MRI safety test results** **MRI safety labelling**	MR safety of implants must be established following relevant harmonised and/or international standards such as ASTM standards. Include test protocols, reports and associated labelling (if not already included in the labelling section above). • MRI safety characterisation should be undertaken according to the ASTM standards or ISO/TS 10974:2018 as appropriate depending on the nature and classification of the device. This information must be related back to the safety and performance requirements of the device while allowing a clinically acceptable MRI to be performed. If this Technical Specification is not used as guidance, justification should be provided for the validity of assessment methods and conclusions. • The guidelines of the Design Verification section of this document should generally be applied during the MR safety assessment. • If RF test results are considered representative of a group of devices (i.e., worst-case devices or comparative devices) extensive justification should be provided, typically including objective evidence. • An MRI safety assessment summary should be provided, with evidence that hazards associated with each clause of ISO/TS 10974:2018 have been assessed and appropriately mitigated if necessary. • Labelling/IFU related to MRI safety should be provided. Details of any assumptions and configurations used in the assessment should be disclosed in the labelling/IFU. It is important that the labelling/IFU clearly communicates which scenarios and configurations have been shown to be safe, and which are untested. • Evidence that any safety critical labelling/IFU is clear and correct and can be accurately interpreted by the typical user (MR technologists and/or radiologists), should be provided. • Assessment of the clinical benefit of allowing patients to get MRI vs. the residual risk.
Declaration of Conformity	
Draft Declaration of conformity provided as per Annex IV of MDR	The EU Declaration of Conformity should include all the information listed in MDR Annex IV.

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Additional information for Artificial Intelligence (AI) /Machine Learning (ML) devices or devices that incorporate AI/ML	
Description of the AI/ML model(s) incorporated in the system/device	Description of the intended use of the AI system, the intended users and operational environment (EN 82304-1). Description of AI system lifecycle (ISO/IEC 5338), including decisions on the model, algorithm selection and continuous validation.
Description of the datasets used in training/testing the AI/ML model(s)	• Data sources and collection processes (ISO/IEC 5259-4, ISO/IEC TR 24028, EN ISO/IEC 8183). • Data generation processes (for simulated data) (BS/AAMI 34971). • Data cleaning, filtering, processing, augmentation processes, by specifying methods and libraries employed and including how consistency between different data sources is guaranteed (e.g., for data obtained by different measurement methods). • Data labelling and annotation processes, including the competence of the labellers (and how that competence is achieved and maintained). • Dataset partitioning processes (ISO/IEC TR 24028, ISO/IEC TS 4213). • Description of features contained in dataset(s) (ISO/IEC TR 24027). • Size of dataset(s). • Data retention and storage processes, including dataset version control, mapping between models and datasets used to generate them.
Description of the processes, tools and environments used to train, test and deploy the AI/ML model(s)	• Hardware (screen size, screen resolution, memory, network connection, etc.) and software (e.g., operating system, browser, run-time environments) environments used for model(s) training (with attention to known vulnerabilities of the libraries employed). • Hardware (screen size, screen resolution, memory, network connection, etc.) and software (e.g., operating system, browser, run-time environments) environments used for model(s) **testing** (with attention to known vulnerabilities of the libraries employed).Hardware (screen size, screen resolution, memory, network connection, etc.) and software (e.g., operating system, browser, run-time environments) environments used for model(s) **deployment** (with attention to known vulnerabilities of the libraries employed).Methodology used for model training, including hyperparameter tuning and processes to ensure reproducibility of results. • Methodology used for model testing, including processes to ensure reproducibility of results. • Methodology used for model deployment, including information regarding how the model(s) behave if the inputs do not meet the specified requirements, availability and interoperability of the model(s), how failures of the system are detected and handled, and compatibility between training and deployment environments if applicable (including the cases in which different programming languages have been used for training/deployment). • Methodology of the change management plan, including but not limited to continuous learning, model re-training, trigger criteria, data sources for re-training. Description of how the AI model(s) accounts for the possibility that its predictions may influence user behaviour or system outcomes, and the mechanisms in place to monitor and mitigate feedback loops, if applicable, that could bias future predictions.

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Description of the processes, tools and environments used to train, test and deploy the AI/ML model(s) - *continued*	Description of the roles involved in the AI lifecycle, of the skills for each of such roles. Records of competence of personnel involved in the AI lifecycle (internal and external resources). Methodology related to explainable AI techniques implemented to foster transparency and explainability of the model(s), if applicable.
AI/ML Risk Management	• Risks related to dataset quality, representativity and size. • Risks related to dataset collection and processing processes. • Risks related to choice of environments and methodologies for training, testing and deployment of models (including time constraints related to the speed at which the system must generate the outputs). • Risks related to model performance (with reference and comparison to state-of-the-art and clinical benefits), including bias/fairness, robustness (including expected value ranges for the model(s) outputs and validation of those ranges and confidence intervals within which performance metrics may vary), concept drift – with a description of how stakeholder requirements are translated into target performance specifications. • Risks related to AI transparency, autonomy, misuse, human oversight, trustworthiness and usability, including operational limits within which the model(s) operates, the factors that can have a negative impact on the quality criteria, and how the quality of the model's outputs is communicated to the user. • Risks related to AI-specific cybersecurity, including adversarial attacks , data poisoning. • Risks related to change management plan, including but not limited to continuous learning, model re-training, trigger criteria, data sources for re-training.
AI/ML Requirements	• Requirements related to dataset quality, representativity and size. • Requirements related to dataset collection and processing processes. • Requirements related to choice of environments and methodologies for training, testing and deployment of models (including time constraints related to the speed at which the system must generate the outputs). • Requirements related to model performance (with reference and comparison to state-of-the-art and clinical benefits), including bias/fairness, robustness (including expected value ranges for the model(s) outputs and validation of those ranges and confidence intervals within which performance metrics may vary), concept drift – with a description of how stakeholder requirements are translated into target performance specifications. • Requirements related to AI transparency, autonomy, misuse, human oversight, trustworthiness and usability, including operational limits within which the model(s) operates, the factors that can have a negative impact on the quality criteria, and how the quality of the model's outputs is communicated to the user. • Requirements related to AI-specific cybersecurity, including adversarial attacks, data poisoning and further risk sources, and security lifecycle. • Requirements related to the change management plan, including but not limited to continuous learning, model re-training, trigger criteria, data sources for re-training.

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AI/ML Verification and Validation

- V&V related to dataset quality, representativity and size.
- V&V related to dataset collection and processing processes.
- V&V related to choice of environments and methodologies for training, testing and deployment of models (including time constraints related to the speed at which the system must generate the outputs).
- V&V related to model performance (with reference and comparison to state-of-the-art and clinical benefits) including bias/fairness, robustness (including expected value ranges for the model(s) outputs and validation of those ranges and confidence intervals within which performance metrics may vary), concept drift – with a description of how stakeholder requirements are translated into target performance specifications.
- V&V related to AI transparency, autonomy, misuse, human oversight, trustworthiness and usability, including operational limits within which the model(s) operates, the factors that can have a negative impact on the quality criteria, and how the quality of the model's outputs is communicated to the user.
- V&V related to AI-specific cybersecurity, including adversarial attacks, data poisoning and further risk sources, and security lifecycle.
- V&V related to the change management plan, including but not limited to continuous learning, model re-training, trigger criteria, data sources for re-training.

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Appendix B

Click on the guidances to access them

Reference Documents

Note: guidance related to MDR issued by MDCG and other entities is evolving at a rapid pace. These links are intended for reference only. Please ensure that the latest version of the documents is used. Gaps with the MDR have not been assessed for each guidance, but guidance documents are included here for general additional information on specific topics. The following is not an exhaustive list and other relevant guidance documents not listed below may be available under each subject/topic.

Guidance for Directives

Guidance for Regulations

MDCG Guidance

Guidance from NBOG

Guidance from IMDRF

Guidance from NBCG-MED and Team-NB

Guidance from CAMD

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Click on the guidances to access them

Specific topic guidance

Quality management Systems Guidance

EN ISO 13485 - Medical devices - Quality management systems – Requirements for regulatory purposes.

Risk management guidance

EN ISO 14971 - Medical devices - Application of risk management to medical devices.

Clinical Evaluation guidance

- **EN-ISO 14155** Clinical investigation of medical devices for human subjects - Good clinical practice.
- **Clinical evaluation:** Guide for manufacturers and Notified Bodies - MEDDEV 2.7.1
- **MDCG** documents on clinical evaluation and related topics.

Biological safety

EN-ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

PMCF g-uidance

MEDDEV 2.12-2 Post Market Clinical Follow Up Studies

Standards

- **EU Harmonised Standards**
- **BSI Online Standards**
- **ISO Online Standards**
- **ASTM Standards**

Shelf-life

ICH Guidelines Q Series

Transit testing

ISTA guidelines

Guidance on devices incorporating ancillary medicinal substances or ancillary human blood derivatives

EMA/CHMP/578661/2010 - EMA recommendation on the procedural aspects and dossier requirements for the consultation of the EMA by a Notified Body on an ancillary medicinal substance or an ancillary human blood derivate incorporated in a medical device or active implantable medical device.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

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