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Article 117

Documentation submission best practice guidelines

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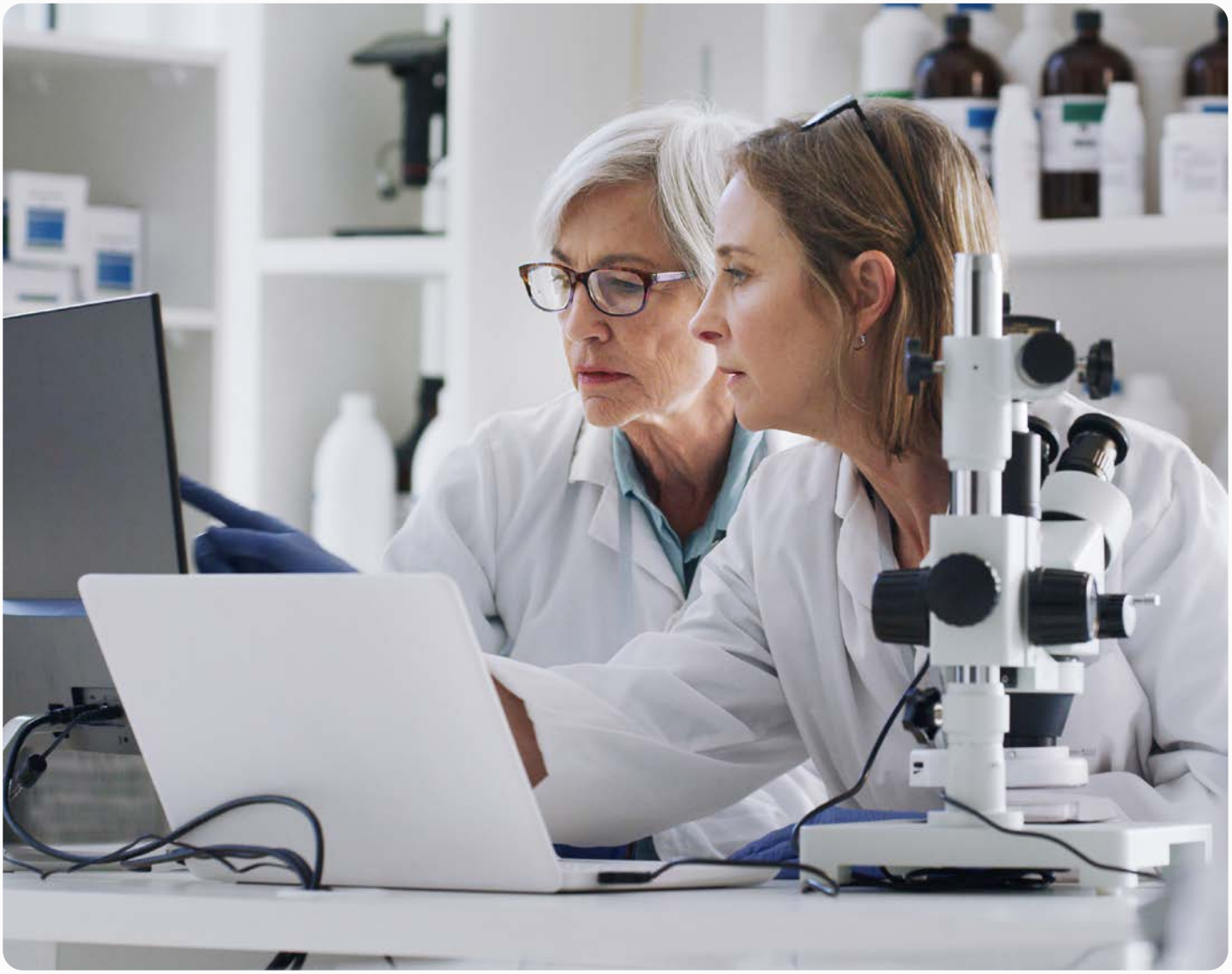


Introduction

Article 117 of the Medical Devices Regulation (MDR) has introduced the requirement that where applicable, Marketing Authorisation Applications (MAA) for Medicinal Products that have an integral delivery device, submit a Notified Body Opinion (NBOp) for the device component of the Medicinal product. The scope of this NBOp is to confirm whether the device component is compliant with the relevant General Safety and Performance Requirements (GSPR).

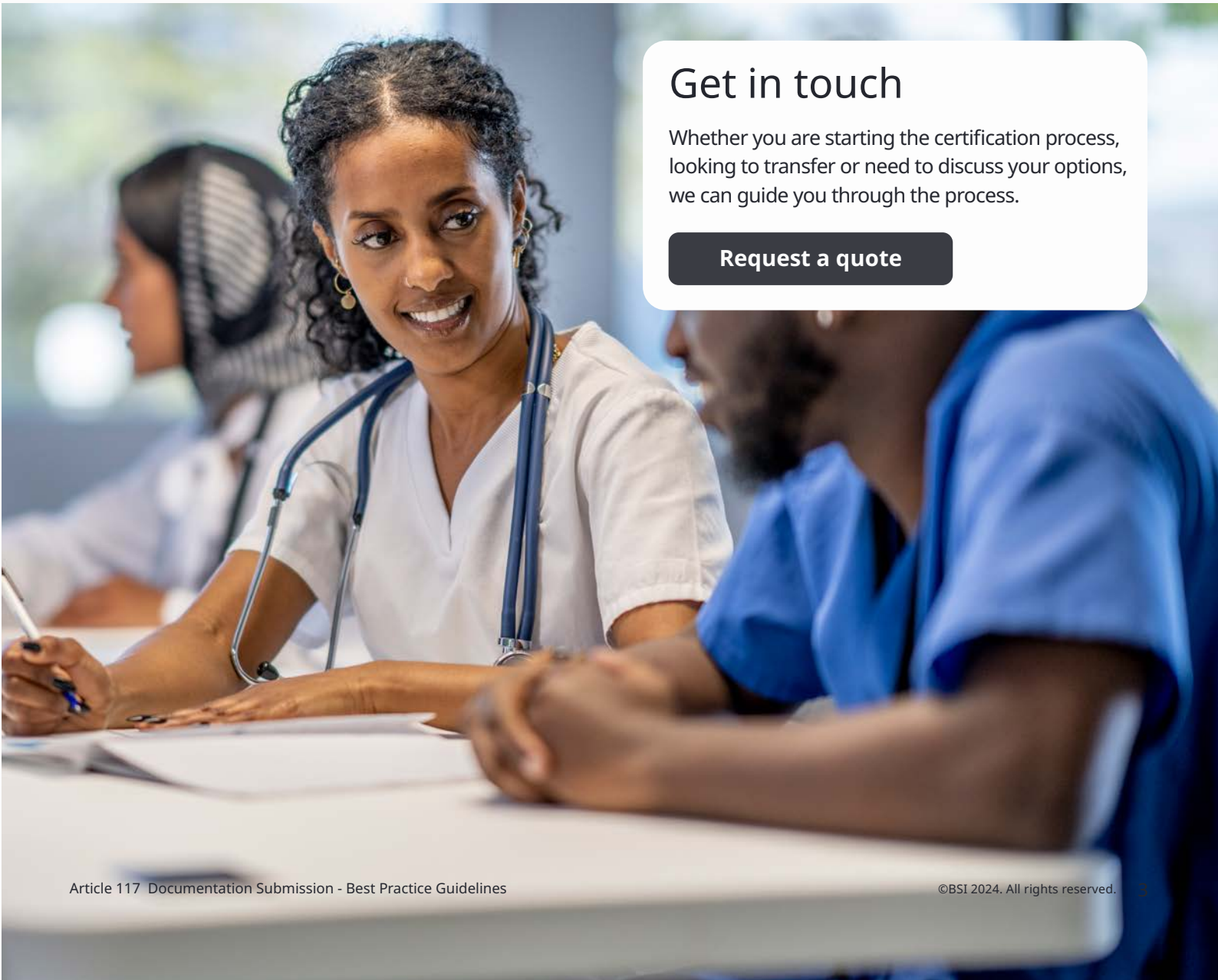
This technical documentation submission guidance is aligned to the requirements of (EU) 2017/745 Medical Devices Regulation (MDR) Annex I and follows the structure given in Annex II of (EU) 2017/745.

This document has been generated from BSI's extensive experience in the conduct of Article 117.

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, and share feedback with Article 117 applicants, BSI Medical Devices proposes the present Best Practice Guidelines for Article 117 Documentation Submission.



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.

Request a quote

Submission and Technical Documentation content

Requirements 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:

- NBOp # reference(s) (if known).
- The type of review (new product, variation, line extension, etc).
- Brief product description, including model numbers involved, etc.
- BSI Ref. number (Service Management Order (SMO) #) for any other relevant submissions (e.g., concurrent applications that may affect the submission).
- An explanation of what has been submitted and how it demonstrates compliace
  For changes to existing certification:
  - What is affected (packaging, material change, life, etc.).
  - What is not affected (along with appropriate justification).

2 The technical documentation

For initial approvals, a complete submission with all the relevant technical documentation providing evidence of conformity to the applicable GSPRs included is required.

To assist Article 117 applicants 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 this document. Guidance on each of the items requested can be found in Attachment A of this document. Additional guidance may be found in reference documents listed in Attachment B.

For submissions in the context of line 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.).
It may be useful to provide a document outlining the similarities and differences to previously approved files, with appropriate references.

3 Authorisation for work to be conducted

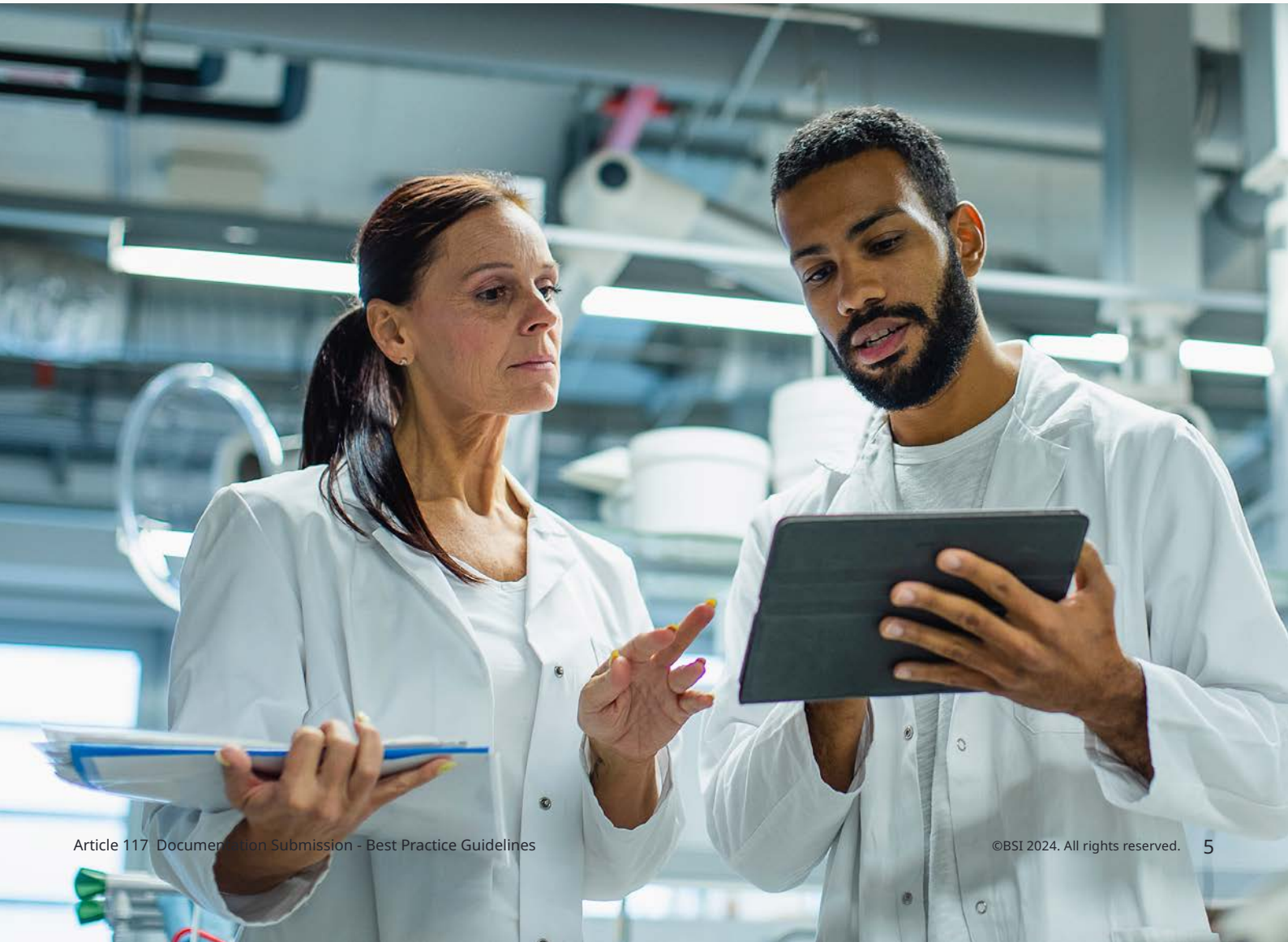
A signed approved quote or work authorisation form (MDF4900) will be required before work can commence. If this is not already in place, please contact your BSI Scheme Manager or BSI Sales Team.

Change Notification Form

If the submission is for a change to the device parts of an existing, marketed product, a completed BSI Change Notification form (MDF4900) will be required with the submission.

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

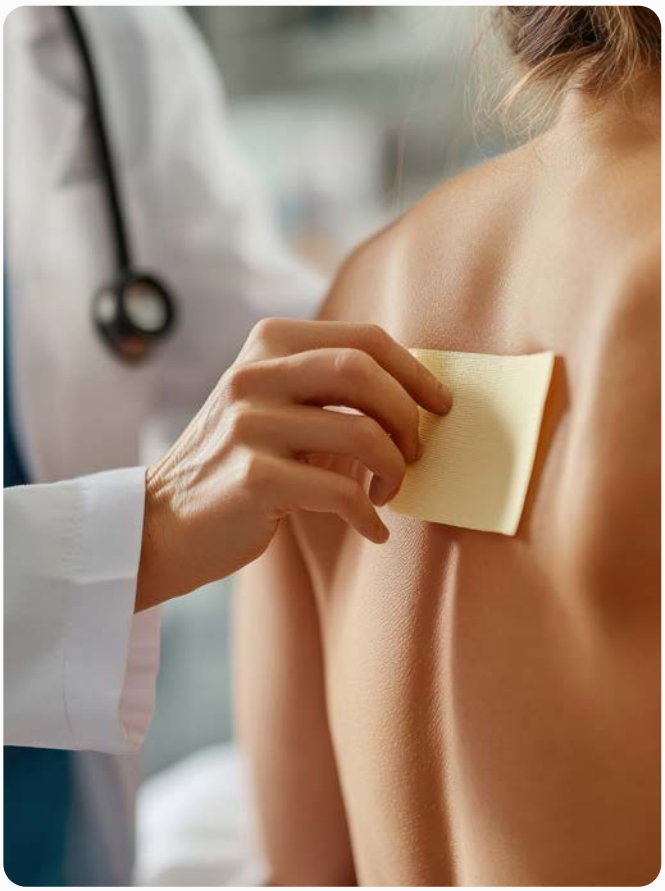
Language

The official language of BSI is English, and all submitted Technical Documentation and test results must be in the English language.

Electronic File Format

Format and file size limits

- Documents should ideally be provided as paginated, fully searchable bookmarked PDF files (see below sections for 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. Protected documents will slow down the review.
  - 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. An index of provided documents, including document title, number, revision etc, should be provided.



- Documents should be bookmarked to ensure ease of navigation (see section below for more information relating to bookmarking). When files are not organized 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 covering all of the parts specified in the table below.** 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.

Parts	MDR Cross-references
Part A - Device description and specifications including variants and Accessories	Annex II, Section 1
Part B - Information to be supplied by the Manufacturer	Annex II, Section 2
Part C - Design and manufacturing information	Annex II, Section 3
Part D - General safety and performance requirements	Annex II, Section 4
Part E - Benefit-Risk analysis and risk management	Annex II, Section 5
Part F - Pre-clinical information (If this section contains 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
Part G - Clinical evaluation, if relevant	Annex II, Section 6.1.c, 6.1.d
Part H - Information related to: • Medicinal substances incorporated in the device • Animal/human tissue derivatives or cells or other non-viable biological substances	Annex II, Section 6.2.a, 6.2.c
Part I - Sterilisation of device parts	Annex II, Section 6.2.e

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 major 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 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).

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.

b Following review of the application a formal quotation will be provided.

c Once the signed approved quotation/ authorisation (see sections above) has been returned by the applicant, BSI will assign the relevant Article 117 references and/or unique identification number (task 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 The assessment of the documentation review can be planned upon receipt of the signed quote or when estimated dates for submission of the technical documentation are provided to BSI.

Additional topics to consider when preparing Technical Documentation for submission

Article 117 applicant personnel support

As an Article 117 applicant, please ensure appropriate resources (e.g., RA, QA, R&D, Manufacturing, etc.) are available during technical documentation review. The more quickly information can be provided, the more quickly 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.

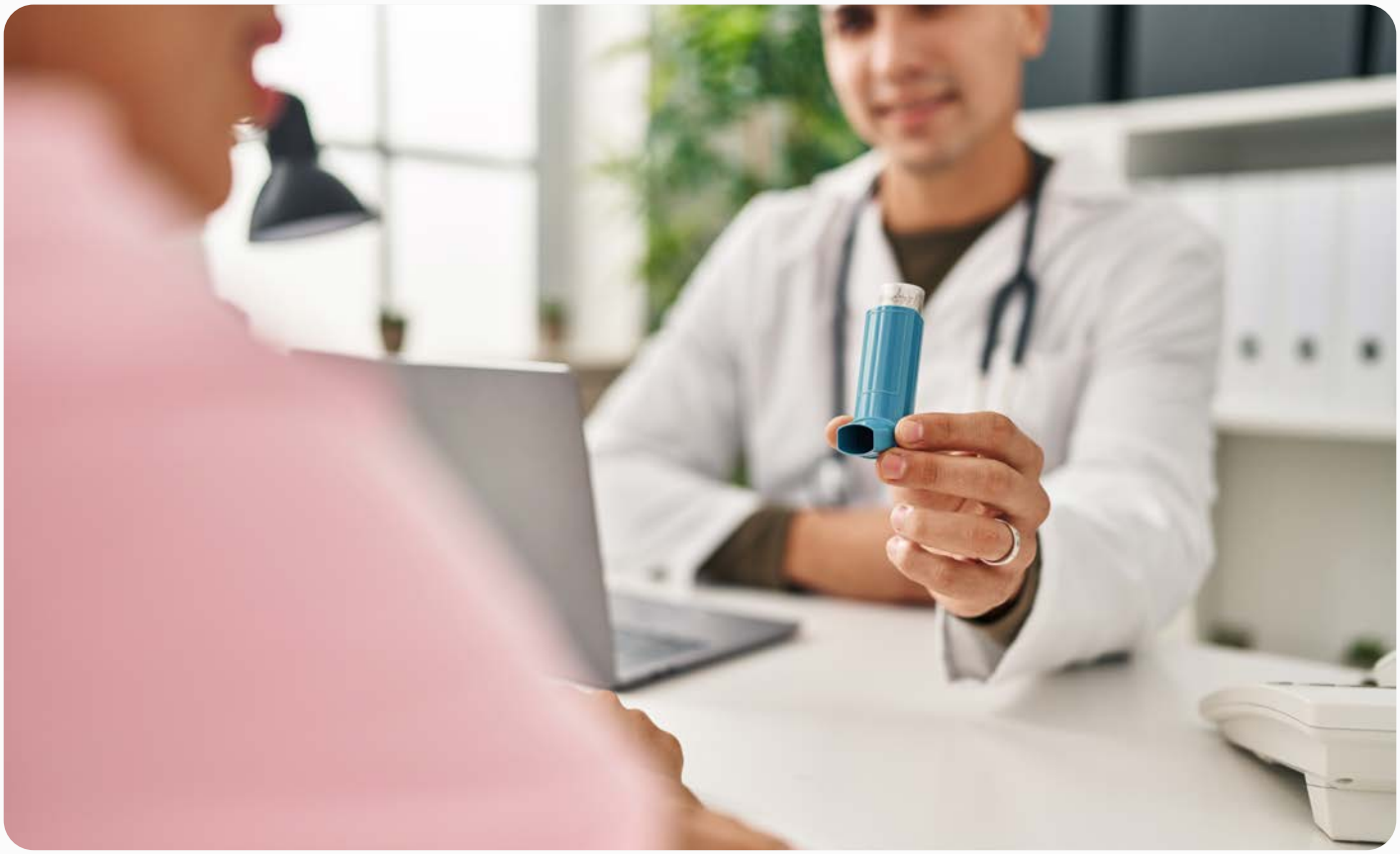
Languages

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

Novelty

Are any new (new to the applicant or new to medical treatment) or innovative materials, processes, assemblies or techniques associated with the devices?

- Additional experts may be involved for novel or high-risk materials, manufacturing processes, devices or indications. These may include toxicologists, statisticians, clinical users, etc.



Attachment A

Information to provide in a Technical Documentation Submission

Note where the table below will refer to the Device, please interpret this as shorthand for Product with Integral Device Parts' or 'integral device part(s) of medicinal product".

Medicinal product description and specifications including variants and accessories	
Medicinal product with integral device parts description	
General description including product or trade names, principles ofoperation, mode of action etc.	The product 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 etc. Sufficient information should be provided to distinguish different variants of the device, and the intended purpose of different design features. 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, 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.

Intended purpose and intended users	
Intended purpose including any clinical claims	The intended purpose or intended use 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. • Although the principal action is medicinal and will be reviewed by the Competent Authority, sufficient information with respect to use is required in order to understand the relative risk of use of the device parts. • 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 specialty, clinical nurses, lay persons, etc.).
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 variants should be provided.
Classification	
Classification of the device including all the applicable rules and relevant rationales	Please confirm the device falls under the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 and therefore the scope of Article 117. Confirm the product when placed on the market: **1** the device and the medicinal product form a single integral product. **2** intended exclusively for use in the given combination. **3** which is not reusable. Please indicate the best fit device classification and rationale per MDR Annex VIII. 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. It is recognised the classification rules are for medical devices and not device components of medicinal products. Classification is to ensure this conformity route is appropriate and to identify the overall risks (e.g., implantable device, electronics etc).

CE marking	Do the device parts have a CE mark? Do any of the sterile components/ containers/devices have CE marking? The document should clearly indicate if components or accessories are provided in a sterile state and include details of the process (see also section Devices with a measuring or diagnostic function). The documentation should also identify if any of the components have already been CE marked as a medical device in their own right, (i.e. non-integral to the medicinal product). Please include a copy of the certificate or Declaration of Conformity.
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).
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 parts have been manufactured utilising any human, animal-derived materials or other non-viable biological substances. Materials which are or include derivatives of human or animal tissues should be clearly identified, such as tallow derivatives.
Bill of Materials	Submission should include the device bill of materials.
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.
Overview of similar devices available in EU or other markets	Provide an overview of identified similar devices available on the EU or international markets, if such devices exist.

Information supplied by the manufacturer

User information

Device or product labelling, (e.g. Draft Summary of Product Characteristics (SmPC) or Patient Information Leaflet (PIL))	It is recognised the labelling must comply to the Medicinal Product Directives and GSPR 23 subparts are not relevant. However, it is still necessary that any labelling relating to use of the device, dosing accuracy, safety and communication of risks are submitted as part of the technical documentation package.

Design and manufacturing information

Design stages

Summary of design stages applied to the device	MDR Annex II requires the applicant to provide “information to allow the design stages applied to the device” to be understood. Provide the design procedure. 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 what test reports have superseded and should be reviewed for each relevant specification.

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, applicants 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. 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, Manufacturer may simply point to the relevant sections of the technical documentation where this information can be found. • Design information with respect to the final combination product, function, performance, lifetime, shelf life, packaging, labelling, regulatory requirements, usability and packaging etc is expected. • For products with multiple components please provide design information s for the top-level subassemblies particularly if those subassemblies are design/manufactured by a subcontractor. Establish a clear traceability with the final product design, and also verification and validation records.
User requirements	Please clearly identify the user requirements for the device.

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, covering the device components as well as the final product. This should clearly identify any special or proprietary processes, and any subcontracted processes. Provide a brief description of each process step including inspections. The manufacturing of the medicinal substance is under the remit of the Competent Authority. The manufacture of the device parts and information on the assembly of the device parts into the final product, including in-process and device related product testing, are required. Provide an overview of processes for the final phases, which may include incoming inspection, in-process controls, final assembly process and testing, labelling and packaging. As a general principle if any of the information requested in the Manufacturing section is not available in English, the applicant 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, it is acceptable to annotate English translations of relevant words within the reports
Critical process verification protocols/plans	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 applicant 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. For device parts this information may be available from suppliers. If not accessible to the applicant they may be shared directly with BSI.
Critical process verification reports	A detailed overview of the manufacturing processes should be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes, including from critical suppliers. Provide a brief description of each process step including inspections. As a general principle if any of the information requested in the Manufacturing section is not available in English, the documentation 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 applicant may annotate English translations of relevant words within the reports.

Critical process validation protocols/plans **Critical process validation reports**	As a part of the initial submission, the documentation should include validation protocols/plans/reports for processes that are validated and are considered critical for the safety and performance of the device. BSI Reviewers may request this information for other validated processes (not originally included with the submission) during the review process if required. For device parts, this documentation may need to be requested from suppliers.
Incoming inspections and acceptance criteria & results from a sample batch **In-process inspections and acceptance criteria & results from a sample batch** **Final inspections and acceptance criteria & results from a sample batch** **Installation and commissioning tests**	Technical Documentation should include the following: • Acceptance criteria and results of incoming inspections from a sample batch for the critical raw materials and/or device parts and/or sub-assemblies and/or components. • Acceptance criteria and results of device related in- process inspections from a sample batch for the critical processes identified in sections above. • Acceptance criteria & device related results of final inspections from a sample batch for the finished devices. • Identification of party responsible of inspections of subcontracted processes. **Note:** the same sample batch should be presented across all inspection steps.
Sites involved in design and manufacturing activities	
Market authorisation applicant (MAA)	The application should identify the name and location of the MAA who is placing the product on the market. This will be included on the NBOp.
Site with design responsibility	The site(s) responsible for design should be clearly identified. This may be the same as the applicant or may be another internal or external subcontractor site.
Sterilisation subcontractors	The name and address of any sterilisation subcontractors for the device parts should be identified, along with the service or material supplied by each. Provide copies of critical subcontractor ISO 13485 or sterilisation standard certificates.
Other critical subcontractors and crucial suppliers relevant to the device(s) including copies of certification held by such entities	For example, device component suppliers.

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 and Performance Requirements (GSPRs) of Annex I is important to ensure that your reviewer can locate the documentation supporting compliance with each of the GSPRs.

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 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.

Standards applied including whether applied in part or full along with the version/date of the standards applied	The documentation should demonstrate that all Common Specifications (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). 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 not been applied in full, appropriate justification should be provided in the technical documentation. A summary or gap analysis regarding ability to comply with associated General Safety & Performance Requirements (Annex I), and a risk analysis & 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. For changes requiring a new NBOp, 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 files meet the state of the art, including consideration of revised or replaced standards or CS.

Benefit-risk analysis and risk management

Risk Management should encompass all stages of design, manufacture (including packaging) and use. Therefore, this information may come from subcontractors, suppliers as well as the final medicinal product manufacturer/MAA.

- A clear roadmap of risk traceability to the finished combination product should be provided.
- The overall risk management process should be documented.
- A description of how different risk ranking, and criteria have been translated and interfaced with each other as relevant.
- EN ISO 14971 and EN 62304 should be considered when estimating risks or identify risk control measures.

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 product(s) under review. The assessment must demonstrate that the benefits outweigh all the residual risks when the device is used as intended.

Risk management

Risk management procedure	Please provide an overview of the risk management process and how risks are assessed, mitigated and reduced. 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 disposal). The analysis must demonstrate that appropriate controls (design out then protective measures) have been applied to all risks. Provide copies of the appropriate risk management documents including a copy of risk management procedure.
Risk management plan	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	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. **Note:** device/components suppliers risk assessments may be applicable here.
Production/process risk assessment	Provide the documented risk assessment for the production/ manufacturing process aspects of the device.
Use risk assessment	Provide the documented risk assessment for the clinical usage/ application aspects of the device.
Risk management report	Provide the risk management report associated with the device.
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.
Material characterisation test protocols and reports	Provide a clear, thorough description of materials used in the device parts and including the primary packaging. Include all material characterisation test protocols and reports and final toxicological assessment on residuals. • In particular, 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 must meet requirements in the MDR for justification of the presence of these substances above 0.1% w/w threshold. See section 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 to confirm the information and the presence of these substances.

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. Supporting evidence for parts/ components should be clearly referenced.
Overall biological safety assessment	Biological safety assessments should be undertaken in accordance with ISO 10993-1. 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 MAA's interpretation of each of the biocompatibility tests along with the overall biological safety assessment. This includes parts/components from suppliers.
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.

Electrical safety and electromagnetic compatibility (EMC)
If not applicable, please indicate in the technical documentation.

Electrical safety test protocols	Please provide the test protocols and reports for electrical safety testing, if applicable to the device. Ensure the provided documentation clearly defines the essential performance of the device and is in line with the risk management documentation. For standards for which compliance is claimed, a clause-by- clause checklist is expected to be provided. Clauses considered non-applicable need to be clearly justified.
Electrical safety test reports	Please provide the test protocols and reports for EMC testing, if applicable to the device. Ensure the provided documentation clearly defines the essential performance of the device and is in line with the risk management documentation.
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 test report to state-of-the-art standards.

Software verification and validation	
EN 62304 checklist	Appropriate documentation is required if the device parts 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. 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.
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 software requirements specification.
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 software requiremnts analysis are allocated to the software items thatcomprise 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.

Software detailed design	For EN 62304 Software Safety Class ‘B’ and ‘C’ software, include the software detailed design (SDD). The software detailed design (SDD) represents a further refinement of the software architecture described in software architectural design section. 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.

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) 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 sysyem. 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 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). **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.

Stability, including shelf life

The stability of the medicinal product is under the remit of the Competent Authority; however, evidence of the stability of the device components is required for the NBOp.

a Evidence should be provided to support device- function related aspects of the final product only.

b The drug related parameters of the final product are outside the scope of the review, so a condensed version of the stability data relating to device aspects may be presented.

c Stability protocol and Reports should be provided, not just summary data.

d Shelf-life may be justified with reference to accelerated data. However, clear justification with reference to ICH guidelines should be provided.

Data for sub-components parts of the finished product should be included in the documentation.

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 utilized. • 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.

Stability/shelf-life validation protocols (to include both device and packaging performance) Stability/shelf-life validation results and reports	• 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 sterilisatiion section). The Competent Authority will examine the overall stability and drug product specific tests. BSI will examine the device performance related tests. **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. • Where complete data to support the proposed shelf life are not available a justification or commitment to provide these data should be made.
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. • 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.
	
	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.
	
	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 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 as compared to the devices previously tested.

Validation protocols and results	Please provide the protocols and results for design validation studies. See also above 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 62355 or other applicable standards. The approach to usability assessment should be appropriate in line with the intended users and intended use • Please provide the protocols and results for usability studies. See also above 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. 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 provide the relevant procedure.

Clinical Evaluation

Clinical evaluation of the principal medicinal product will be carried out by the Competent Authority. It is expected most Article 117 device parts are to aid the delivery of the medicinal product and do not have clinical impact of themselves. In these cases, a clinical review is not performed by the notified body and this section can be marked as not applicable.

In cases where there are device claims relating to the device part (e.g., “less painful injection”) or, where the device is novel or where there are clinical safety risks for the device part (e.g., implants), the clinical evaluation will be required.

Clinical development strategy	If applicable, please explain the clinical development strategy for the device component.
Clinical evaluation plan	If applicable, please provide the clinical evaluation plan documented and used for the device.

Clinical evaluation report	**Note:** Clinical evaluations are required only in the case where there is a clinical claim or clinical safety risk from the device part of the integral medicinal product. In such cases, representative clinical data must be provided for all indications and variants. The clinical evaluation should include all available data relevant to supporting safety and performance of the device. 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). If the device is 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	If applicable, justification should be provided (with appropriate evidence) to substantiate the qualifications of individual(s) conducting/approving the clinical evaluation.
Clinical investigation protocols	For any device parts with clinical claims but without suitable equivalents and / or insufficient data in the literature, pre- market clinical investigation may be required. 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	If applicable to Clinical Investigations • 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	If a Clinical evaluation is provided, a copy of all literature articles selected and analysed within the clinical evaluation report should be included in the technical documentation.

Devices incorporating medicinal substances

If the manufacturer considers that Rule 14 and the associated GSPRs to be appliable, please contact BSI for additional information.

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

This section is related to materials that may be incorporated or utilised in the manufacture of the device components which for the purposes of Article 117 applications should consider compliance to Ph Eur 5.2.8 and to the “Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products” EMEA/410/01 Rev 3, July 2011.

Information on the nature of the animal starting tissue, animal species and geographical nature **Animal/Human tissue (or their derivatives) related risk assessment (either stand-alone or as a part of the risk management section)** **Justification for the use of animal/human tissues or their derivatives (including the choice of animal species and tissues) taking into account the balance of residual risk and medical benefit - compared to available alternatives (e.g., synthetics or lower risk animal species).** Risk management documentation in accordance with the requirements of EN ISO 22442-1:2007 (including the procedure for risk management), reflecting all hazards associated with use of the animal tissue 6.8.5 Information to establish compliance with EN ISO 22442-2 Information to establish compliance with EN ISO 22442-3 Evidence to support compliance with GSPR 13.3 for devices utilising non-viable biological substances	The submission should clearly indicate whether the device utilises human or animal- derived cells or tissues or other non-viable biological substances. If the device is a system and includes multiple components, then identify the components which utilise these materials. For devices under the scope of (EU) 722/2012 please contact BSI for additional information. 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 or EMEA/410/01 Rev 3 for any applicable exclusions (e.g., tallow and processing method utilised) from the subcontractor. If in doubt, speak with your Scheme Manager before submitting the 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 and/or a European Agency for the Evaluation of Medicinal Products (EMA).

Devices composed of substances that are absorbed by or locally dispersed in the human body (Rule 21 devices)

If the manufacturer considers this Rule and the associated GSPRs to be appliable, please contact BSI for confirmation and guidance on the documentation requirements.

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	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 the inclusion of 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. 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. Labelling is the remit of the Competent Authority.

Packaging and transit (transport) testing

Packaging drawings and/or configurations	A complete packaging Bill of Materials (BoM) and diagrams including specifications and suppliers should be provided to illustrate how each device is packaged.
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 utilized. 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.

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 utilized. • 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.

Sterilisation

The final assembly and any aseptic filling or sterilisation of the medicinal product is in scope of the Competent Authority assessment where conducted in accordance with pharmaceutical requirements. However where terminal sterilisation is intended to sterilise the external surface of the device using medical device standards, this is in scope of the NBOp and evidence of the validation of the sterilisation processes is required.

The sterilisation of the device components, when purchased non-sterile and used in sterile finished products, is not in scope of the NBOp. Where sterile components are purchased, evidence of the validation of the sterilisation processes is required for the NBOp. Sterile devices which are CE marked (e.g., needles) are outside the scope of NBOp.

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 Inactivation).

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.

Sterilisation validation protocol

Manufacturers should include information on testing and control of bacterial endotoxins (pyrogens) on their devices.

Sterilization validation results and reports

Summary documentation / reports should provide an audit trail to the raw data.

Additional guidance relating to specific document types is provided below.

Sterilization validation – Radiation should include:

- Protocol.
- Justification for selection of product/master product/worst-case representative product.
- Dosimetry mapping data (typically from the sterilization contractor).
- Validation of bioburden testing method & test report.
- Bioburden determination & 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 protocol Sterilization Validation results and reports	**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. **Handling Multiple Routes of Sterilization and/or Equipment** • Validation documentation should include records relating to all sterilization locations. • Documentation should demonstrate completion of validation activities at all locations for all equipment. Validation records shall be traceable to the devices under review.
Devices with a measuring or diagnostic function	
Protocols for tests associated with establishing the device limits of accuracy, precision, calibration etc 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 MEDDEV 2.1/5 for guidance on criteria that qualify a device as having a measuring function.

Devices intended to be connected to other devices to operate as intended

Protocols for tests associated with establishing the safety and performance of the device and the combination while connected to other devices and their interoperability **Reports for tests associated with establishing the safety and performance of 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.

Magnetic resonance imaging safety of implants

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.

MRI safety test protocol

- The guidelines of the Design Verification section of this document should generally be applied during the MR safety assessment.

MRI safety test results

- 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.

MRI safety labelling

- 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.

Attachment B

Click on headings to skip to the web content

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

Regulatory guidance organizations

Guidance for Regulations

MDCG Guidance

Guidance from IMDRF

Guidance from NB-MED and Team-NB

Guidance from NBOG

Guidance from CAMD

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

Standards

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

Shelf-life

ICH Guidelines Q Series

Transit testing

ISTA guidelines

Guidance on documentation for Article 117

- **EMA/CHMP/QWP/BWP/259165/2019** Guideline on quality documentation for medicinal products when used with a medical device.
- **Team-NB Position Paper on Documentation Requirements for Drug Device Combination** Falling in the Scope of Article 117 of MDR 2017/745.
- **EMA/37991/2019** Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746).

Your partner in progress

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