



MDR Documentation Submissions

Best Practices Guidelines

Contents

1	Introduction	3
2	Initial application package for Quality Management System	3
3	Submission and technical documentation contents	4
3.1	Cover letter	4
3.2	The technical documentation	5
3.3	Authorisation for the work to be conducted	5
4	Submission Method	6
5	Document Format	6
5.1	Language	6
5.2	Electronic File Format	6
5.2.1	Format and file size limits	6
5.2.2	Optical Character Recognition (searchable format)	7
5.2.3	Bookmarks	7
5.2.4	Pagination	7
5.2.5	Signatures	8
6	Submission process	8
7	Additional topics to consider when preparing technical documentation for submission	9
7.1	Manufacturer personnel support	9
7.2	Document availability	9
7.3	Certificate scope	9
7.4	Subcontractors	9
7.5	Accessories	10
7.6	Novelty	10
7.7	Additional considerations for technical file desktop audits	10
	Attachment A: Information to provide in a technical documentation submission	12
	Attachment B: Reference Documents	27

1 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 Annexes IX to XI of (EU) 2017/745 Medical Devices Regulation (MDR).

The application documentation described in this document is aligned with the requirements of (EU) 2017/745 Medical Devices Regulation (MDR) for Quality Management System Assessment, described in detail in Annex IX section 2.1, Annex X section 2 and Annex XI section 6.1 of (EU) 2017/745.

The technical documentation submission guidance is aligned to the requirements of (EU) 2017/745 Medical Devices Regulation (MDR), described in detail in Annex II and III of (EU) 2017/745.

Medical Devices Notified Body BSI (BSI-UK / BSI-NL) and medical device manufacturers both have an interest in speeding up the review of Technical Documentation (Summary of Technical Documentation (STED), dossier, technical file, renewal application, etc.) and reducing time to issue certification.

The two most frequent reasons for delays to technical documentation reviews are:

- BSI has not been provided with all of the information needed for the review;
- The information is present within the technical documentation, but is difficult to locate.

To reduce the frequency of the above issues, BSI Medical Devices Group proposes the following guidelines, informally known as "MDR Documentation Submissions: Best Practices Guideline".

2 Initial application package for Quality Management System

For application under Annex IX, in line with section 2.1 of the MDR, the manufacturer's application shall contain a defined set of information and documentation:

- the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business,

Note: After the SRN system has been implemented, the manufacturer shall use the Single Registration Number (SRN) when applying to a notified body for conformity assessment and for accessing EUDAMED in order to fulfil its obligations under MDR Article 29 "Registration of Devices".

- all relevant information on the device or group of devices covered by the quality management system,
- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,
- a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure,
- the documentation on the manufacturer's quality management system,

- a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures,
- a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,
- the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92,
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
- documentation on the clinical evaluation plan, and
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.
- the technical documentation referred to in Annexes II and III for each device to be covered under a product-specific certificate.

For devices which don't require a Product-specific certificate, the technical documentation referred to in Annexes II and III for the devices selected on a representative basis by BSI.

3 Submission and technical documentation contents

Three things are required for any technical documentation review:

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

The submission should therefore contain:

3.1 Cover letter

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

- CE 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 Order's 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 and, for changes to existing

certification:

- what is affected (packaging, material change, sterilisation, etc.)
- what is not affected (along with appropriate justification)

Note: a possible format for this explanation could be a table based on the sections of the technical documentation, as below:

<i>Technical Documentation section</i>	<i>A/NA?</i>	<i>Description of evidence submitted; for changes, impact on compliance or rationale for why this section is not affected</i>
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3.2 The technical documentation

To assist manufacturers in determining the correct information to provide to BSI, guidance is provided in Attachment A. Associated reference documents are listed in Attachment B for additional guidance.

Please note that, 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 or not there have been any changes affecting its relevance to the current application, etc.).

3.3 Authorisation for the work to be conducted

The following will be required before work can commence:

- A signed approved quote
- or
- A signed BSI Work Authorisation form* (for existing clients and certificates only)

**Form MDF4510, MDF4511, MDF4512, MDF4513, or MDF4514 depending on the location of the legal manufacturer (UK, US, Eurozone, Canada, or China, respectively)*

4 Submission Method

- **The preferred route for submissions is via the secure BSI document upload 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.
- Alternatively, documents may be submitted by email. This route is normally only feasible for small submissions requiring relatively few documents of small file size.
- If necessary, you may submit a CD/DVD version of your documentation. Acceptable formats for CDs are CD-R, CD-ROM, CD-RW, DVD-R, and DVD-RW. Other formats may not be readable by all BSI computer systems. The same rules apply if the CD contains multiple files. Please note that CD/DVD submissions 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 need to receive a hard copy of the information.** If hardcopies are received *in lieu* of electronic files, these will need to be converted to the format described in section 4 below by our administration team. This will add time and cost to the review.

5 Document Format

5.1 Language

- The official language of BSI is English, and all submitted Technical Documentation and test results should be in the English language. Technical Documentation in other languages may result in additional review time and costs for translation which will be passed on to the applicant, and subject to BSI terms covering costs.
- Technical Documentation for Class III and Class IIb implant-products must be available in the English language. The primary language for all audit related documents is English.
- Technical Documentation for Class IIa and all other IIb devices may be accepted in another EU language as long as the Competent Authority does not require Technical Documentation to be in a prescribed language and that BSI is able to allocate technical reviewers with correct competencies and language capabilities.
- Technical documentation for Class I devices which are placed on the market in a sterile condition, have a measuring function, or are reusable surgical instruments may be accepted in another EU language as long as the Competent Authority does not require Technical Documentation to be in a prescribed language and that BSI is able to allocate quality system and/or microbiology auditors with correct competencies and language capabilities.

5.2 Electronic File Format

5.2.1 Format and file size limits

- **Documents should ideally be provided as paginated, fully searchable bookmarked PDF files** (see section 5.2.2 and 5.2.3 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.

- **PDF files and attachments should not be file protected or locked as this prevents necessary access and file manipulation for archiving.**
- **Documents should be bookmarked to ensure ease of navigation** (see section 5.2.3 below for more information relating to bookmarking).
- **Documents should be collated into a single document if possible.** If this is not possible due to file size, the submission should be collated into the smallest number of individual files possible. Separate submissions will need to be indexed and consolidated, which may add to the time and cost of the review.
- If the information is uploaded to the website as multiple separate small file size documents, these may be processed into one PDF file. To aid this process, please indicate the order in which the documents should be compiled. A logical numbering of files is preferred (e.g. using 1, 2, 3...at the beginning of the title of each file).

Once BSI has the information, we will make any adjustments as necessary (e.g., OCR it, bookmark it, paginate it and add headers and footers as required). The marked-up PDF becomes the final archived version.

5.2.2 Optical Character Recognition (searchable format)

- Manufacturers scanning directly from a printed page 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.

5.2.3 Bookmarks

- Bookmarks are requested to aid in locating major sections of the technical document. At a minimum, sections in MDR Annex II "Technical Documentation" (or the GHTF STED sections) should be bookmarked.
- 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.

5.2.4 Pagination

- Each page of the submission should have a separate, sequential page number, starting with 1. It doesn't matter how many pages, volumes, or binders are submitted – each page should have a unique number.

- PDF files are automatically numbered. When referencing page numbers, please be clear as to whether the original dossier page or the PDF file page is being used.
- Pagination is not mandatory, as BSI can add this with our software. Documents received without proper pagination however will incur added review time to properly format.

5.2.5 Signatures

Signatures are required for any signed document in the file, including signed quotes and BSI Work Authorisation Forms. Signatures can be handled in a number of 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.

6 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 (<https://www.bsigroup.com/en-GB/medical-devices/forms/contact-us/>). 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) If a Work Authorisation Form is required, ensure that the form is signed, dated, and completed with the following details:
 - Company Name and Title of Submission
 - Details of the certificate(s) affected (certificate numbers starting with CE; for Class III devices and Class IIb implantable devices this will typically be an EU Technical Documentation Assessment certificate rather than an EU Quality Assurance certificate).
 - Appropriate box ticked to indicate review speed required (Regular/Fast Track/Dedicated/On-site)
- c) Once the signed approved quote or Work Authorisation Form (see Section 2.3 above) has been submitted, BSI can assign a reviewer. At that time BSI will assign a unique identification number ("SMOxxxxx") (i.e. Service Management Order number) for your review and contact you with that number. We ask that you reference those numbers in any email correspondence with BSI during the review process.
- d) The review process will begin upon receipt of the submission (Section 2) AND the signed quote / signed BSI Work Authorisation Form.

7 Additional topics to consider when preparing technical documentation for submission

7.1 Manufacturer personnel support

Please ensure appropriate manufacturer resources (RA, QA, R&D, Manufacturing, etc.) are available during On-site or Dedicated reviews. The more quickly information can be provided, the more quickly questions can be closed and certificates issued.

7.2 Document availability

If a pointer system is used for technical documentation, ensure key documents supporting each section are made available to the reviewer/auditor at the time of the initial submission. If these documents are not provided, much of the first round of questions may be devoted to asking for them, which will delay the start of the full review. Please remember that the reviewer must see the manufacturer's conclusions regarding compliance, as well as the objective evidence necessary to support those conclusions.

7.3 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., 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 product 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.

7.4 Subcontractors

Are there any changes to subcontractors related to the application?

- All significant subcontractors must be added to associated EU Quality Assurance certificate(s) and 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 is significant, discuss with your Scheme Manager.
- Subcontractors which 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. TUV Americas) may require a subcontractor audit, depending on the scope of their activities and the verification activities undertaken by the manufacturer. Please ensure that these details are made clear in the application.
- If design is subcontracted, control of this subcontracted activity must be considered.

7.5 Accessories

Are any new devices or instruments used *with* the products under review? If a Class III device, for example, requires the use of new Class IIa, Class Im or Class Is equipment which is not within the scope of the existing Quality Management System certification, additional Technical Documentation File reviews may be required for these accessories.

Please provide the following information for any accessories associated with your 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)
- Evidence of compatibility with the subject devices (e.g., in accordance with Safety & Performance Requirement 14.1 and 14.5 of MDR)

7.6 Novelty

Are any new (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.
- 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 with your Scheme Manager to select the most appropriate review option.

7.7 Additional considerations for technical file desktop audits

Surveillance audits of Class IIa and IIb technical files may take place on-site or as a remote “desktop” audit. In an on-site audit, auditors can easily request additional documents or ask questions in real time, but for desktop audits, it is important that all necessary information is included to avoid delays once the reviewer has set aside time to review the file.

Please provide the following information for technical file desktop audits:

- Main technical file body as well as key supporting documents or attachments. In general, if a document is listed as evidence in the Checklist for the General Safety & Performance Requirements, the reviewers may expect to review that document as evidence of compliance with the General Safety & Performance Requirements;
- Manufacturer’s current number of employees;
- A summary of any changes to the device since the last technical file audit;

- Information on engagement with any global regulatory bodies in respect of legal compliance or other issues;
- Information on any changes to the quality system or management.

Additional review time may be required in the following cases:

- Devices using electronic IFU per Regulation 207/2012
- Self-performed standards compliance testing or alternatives to standards compliance testing
- Class C software per EN 62304 requires additional audit time
- Clinical investigations may require review by a clinical specialist and/or statistician
- Technical Documentation File with poor traceability or incomplete information.

Please note:

- There are NO standards are harmonised to 2017/745 at this time
- MedDev guidance documents have scopes that indicate they are applicable to existing Directives.

Attachment A:

Information to provide in a technical documentation submission

Administrative information	
Manufacturer name and address	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, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the legal manufacturer should be identified.
EU Authorised Representative name and address	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 and Declarations of Conformity. The Single Registration Number (SRN) of the EU Authorised Representative should be identified.
File date and issue number	The file status and revision history should be provided. Individual documents should also indicate date, revision history and status.
Applicable legislations	<p>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:</p> <ul style="list-style-type: none"> • If the device is intended to be used in accordance with both the MDR and 89/686/EEC (personal protective equipment), ensure that fulfilment of the relevant basic health and safety requirements of Directive 89/686/EEC 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, 207/2012) ensure that these are identified and any new requirements met.
Device identification	<p>A complete list of product codes should be provided.</p> <p>GMDN Code and Device Category / Generic Device Group should be identified.</p>
Device classification	<p>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.</p> <p>If the device contains multiple components that on their own might be classed differently, please note:</p>

Administrative information

If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

Related previous submissions

Details of any other submissions relevant to the application, including BSI reference number (SMO) should be provided.

Accessories

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).

Please note (as indicated in Section 6.5 of the main document), evidence should also be provided within the Technical Documentation to demonstrate compatibility of the devices with any applicable accessories

Technical documentation

Device description

The device description should enable understanding of the design, packaging, sterilisation, or other characteristics of the device.

- 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?
- Pictures and schematics should be provided wherever possible to enable an understanding of the device design features and intended purpose.

The Basic UDI-DI assigned by the manufacturer should be provided as soon as device identification becomes based on a UDI system.

Intended use

The intended use should provide sufficient 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 been described consistently throughout the file (e.g. in the IFU, risk management documentation, clinical evaluation report, and design requirements).
- 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.

Market history

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.

Technical documentation	
	<ul style="list-style-type: none"> - Provide evidence (e.g., SMO / EQ references of previous reviews) to demonstrate that BSI has been notified of all significant changes (if applicable). <p>Provide Periodic Safety Update Report (see below)</p>
Sales, complaints and vigilance	<p>Please provide sales, complaints and vigilance data for the last 5 years for your device, if available.</p> <ul style="list-style-type: none"> • 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 noted, or corrective actions taken? What is the status of these actions? <p>Full details of vigilance issues should be provided, including the status of any Field Safety Corrective Actions or Notices. This data should include FSCA or FSN outside the EU, if related to a device which is sold in the EU.</p>
Draft Declaration of Conformity	<p>The EU Declaration of Conformity should include all of the information listed in MDR Annex IV.</p>
Technical Standards and Common Specifications	<p>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). See Attachment B for a link to the most up to date list of harmonised standards.</p> <ul style="list-style-type: none"> • 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. <p>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.</p>

Technical documentation

General Safety & Performance Requirements

MDR Annex II Section 4 requires the technical documentation to include a demonstration of conformity with the applicable General Safety & Performance Requirements (SPRs) of Annex I, including:

- The SPRs that apply to the device and an explanation as to why others do not apply
- The method or methods used to demonstrate conformity with each applicable SPR
- Harmonised standards, 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 SPR. 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.

It is helpful to provide a checklist against the SPRs to show how compliance with the SPRs has been achieved.

Manufacturing process and subcontractors

- A detailed overview of the manufacturing processes should be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes.
- 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.
- If new critical subcontractors are used, provide copies of their ISO 13485 certificates. If a critical subcontractor does not have an ISO 13485 certificate from a Notified Body, additional supplier audits may need to be arranged (see Section 6.4 of the main document for further information).

Validation documents for processes that can affect final product quality should be provided.

User information

Documents should include labels, instructions for use (IFU), and patient implant cards (for implantable devices). Documents may also include surgical manuals, brochures, etc.

- Legible versions of all levels of labels should be provided (e.g. secondary pack, primary pack) and should be representative of the finished form, showing all included symbols.

Technical documentation

- It is sufficient to show information concerning labelling in English only, but items to be translated and the plan for translation should be indicated.
- If possible, provide drawings with the packaging configuration (showing placement of all labels) and label specifications.
- 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.
- It should be clear how the labelling documents are controlled.
- Supporting evidence should be provided for any claims made in the labelling or marketing literature.
- Please ensure that any specific requirements of relevant harmonised standards or CS are addressed in the labels and information for use.

If electronic IFU will be utilised, ensure compliance has been demonstrated with all relevant aspects of Regulation 207/2012.

Design verification and validation

Product design specifications should be adequately documented, outlining the key functional characteristics and technical performance specifications for each device, along with verification / validation tests to substantiate that they have been achieved.

- Overall, manufacturers should demonstrate that design requirements have been identified in accordance with the intended use, safety and performance requirements, risk assessments, and relevant harmonised and other key standards or CS.
- To this end, 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.
- 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.

Technical documentation

- 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 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:
 - Evidence of equivalence 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 tested.

Risk management

A thorough design and process Risk Management assessment should be conducted for the entire life-cycle of the device (from initial design concept up to and including device disposal). This should be updated (as appropriate) with data from PMS.

- 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

Technical documentation

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.
- The analysis must demonstrate that appropriate controls (design out then protective measures) have been applied to all risks.
- Information for use may reduce occurrence of some risks, but it cannot reduce the occurrence of *residual* risks. Please ensure appropriate use and quantification of risk control measures in the risk assessment.
- 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

For line extensions and devices based upon existing devices, the manufacturer may conclude that pre-existing risk management documentation is applicable. However, there are always risks associated with even small changes, and a summary to demonstrate that these risks have been considered (and have been adequately mitigated) should be provided.

Guidance on Risk management Process is available in EN-ISO 14971- Medical devices -- Application of risk management to medical devices

Clinical evaluation

Clinical evaluations are required for all medical devices. For 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 SPRs
- 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, where the clinical evaluation is based on sufficient clinical data and is in compliance with any relevant CS;
- Annex XIV and XV describe Clinical Evaluation and Clinical Investigations, respectively. Guidance is also available in EN-ISO 14155

Technical documentation

Clinical investigation of medical devices for human subjects - Good clinical practice

- It is useful to provide a copy of the procedure for conducting Clinical Evaluation.
- If a pre-market clinical investigation has been conducted, please ensure:
 - 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.
- Representative clinical data must be provided for all indications and variants. Justifications for why one group of data is representative of another must be clearly substantiated.
- 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** (MDR Annex XIV Sec. 3).
- A justification should be provided (with appropriate evidence) to substantiate the qualifications of individual(s) conducting / approving the clinical evaluation.
- Some indications or specific clinical benefit claims may require the Notified Body to consult with an external specialist (a surgeon or similar). Contracting a confidential source that is mutually agreed with the Manufacturer may be time consuming.

For Class III implants and Class IIb active devices intended to administer and/or remove a medicinal product, the Notified Body may be required to also consult the Commission expert panel regarding the clinical evaluation assessment (procedure per MDR Annex IX Sec 5.1). The expert panel may decide whether or not to scrutinise their clinical evaluation assessment report and to provide a scientific opinion. This process will add time to the review depending on whether consultation is required and whether an opinion is provided by the expert panel.

Technical documentation

Summary of Safety and Clinical Performance

For Class III and implantable devices other than 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 in a way that is clear and understandable to the intended user and patient (if relevant), and should contain all of the elements listed in MDR Article 32, Sec 2.
- The Commission may define a form and presentation of data for the SSCP by means of implementing acts. Manufacturers should review requirements at the time of document preparation and submission.

The SSCP should be updated annually (as per Article 61) over the lifetime of the device as needed, and updates should be defined in the Post-Market Surveillance Plan.

PMS and PMCF

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.

- Ensure that the PMS plan adequately justifies the monitoring of the safety and intended performance of the device.
- If Post-Market Clinical Follow-up (PMCF) is not part of the PMS Plan, please ensure that adequate justification is provided, based on the risk and clinical data available for the device.
- 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 in light of data from the clinical evaluation and risk evaluation for that device.
- The Notified Body may be required to periodically review results from ongoing or completed PMCF studies following CE mark certification, including an specialised clinical evaluator in some cases.

See Attachment B for links to guidance for PMS and PMCF.

Periodic Safety Update Report

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. This PSUR should be included in the technical documentation. The PSUR would not be available for an initial submission, but would be expected for devices on the market, per the timelines below.

- The PSUR should contain the elements outlined in MDR Article 86.

Technical documentation

- For Class III and IIb devices, the PSUR should be updated at least annually. For Class IIa devices, the PSUR should be updated when necessary and at least every two years.
- For Class III or implantable devices, manufacturers should submit the PSUR to the notified body when updated. For other devices, the PSURs should be made available to the notified body or to competent authorities upon request.

The PSUR should be updated per timelines above throughout the lifetime of the device.

Biological safety

- 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.
- Additional guidance has been published by the UK Authorities (MHRA). See Appendix B for a link to this guidance.
- Biocompatibility assessments should include evidence of compliance for the **finished device** (including consideration of all materials and all manufacturing steps). It is not sufficient to simply state that devices have been manufactured from materials of well-established biological safety – an assessment which takes into account the impact of manufacturing and sterilisation processes, intended use, etc. must be provided.
- 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.
- A justification should be provided regarding the qualifications of those involved in planning, executing, and analysing the biocompatibility assessment.

Devices including carcinogenic, mutagenic, or toxic to reproduction (“CMR”) substances of category 1A or 1B, or substances having endocrine-disrupting properties must meet requirements in the MDR for justification of the presence of these substances. Specific labelling requirements must also be met for these substances (SPR 10.4.5).

Sterilisation validation

Sterilisation validation is reviewed separately by BSI Microbiology Specialist.

- 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 and sterilisation validation / adoption with respect to parameters recommended in the IFU.
- Documents should describe:

Technical documentation

- use of “State of the art” process validation methods;
- the bioburden controls and monitoring;
- the product qualification (Dose verification, BI suitability testing, SAL calculations);
- the process qualification (Performance qualification, Dose Map, BI Inactivations).
- Additional guidance relating to specific document types is provided below:

Sterilization Validation – Radiation should include:

- Protocol;
- 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

Sterilisation Validation – Ethylene Oxide should include:

- Protocol;
- 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

End User Sterilisation Product documentation should include:

- Instructions for use that detail the validated sterilisation and cleaning parameters. Please be aware that reference to “standard hospital practice” is insufficient;
- Validation report for the sterilisation parameters listed in the IFU;

Validation report for the cleaning parameters listing in the IFU.

Packaging

- Packaging testing should address requirements for both transit endurance and shelf life stability, and be undertaken in accordance with relevant standards.
- A complete packaging BoM and diagrams should be provided to illustrate how each device is packaged.

Technical documentation

- 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.

Any change to packaging is considered a significant change. For Class III devices and Class IIb implantable devices, these must be reported to BSI for review and certificate re-issue.

Shelf life and stability testing

- Shelf life is normally considered to be the time the device can be kept in the packaging prior to 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 testing is based on accelerated age testing, this should be accompanied by a plan for real time testing. Real time testing should be underway by the time documentation is submitted for review.
- Extensions to shelf life for Class III devices and Class IIb implantable devices must be reported to BSI for review and certificate re-issue.

Shelf Life Validation should include:

- Protocol (with acceptance criteria for each test performed) and appropriate test references;
- 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 (temperature and humidity) and how the aging times were calculated;
- A statement covering Real Time Aging plans;
- A clear delineation of statistically significant sample quantities;
- Actual physical/microbiological test data reports supporting the expiration date, or post aging, claim (peel testing, burst testing, dye testing, etc.);

A summary of the ship testing/transit simulation testing conducted and applicable test reports.

Product lifetime

- The lifetime of the device should be defined, and considered relative to other parts of the dossier (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".

Technical documentation

Human, animal, and
Biologically derived substances

The submission should clearly indicate whether or not the device utilises, or is used in conjunction with any human or animal- based products or other non-viable biological 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). If in doubt, speak with your Scheme Manager before submitting a dossier.

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).

Medicinal substances and
substances absorbed or locally
dispersed

The submission should clearly indicate whether or not the device utilises, or is used in conjunction with, any medicinal substances or substances absorbed by or locally dispersed in the human body.

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).

Software

Appropriate documentation is required if the medical devices are either stand-alone software or rely upon software.

- If medical device is stand-alone software, guidance for the qualification and classification of the software is found in MEDDEV 2.1/6. See Attachment B for a link to this guidance.
- 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 medical device directives 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,

Technical documentation

maintenance/change management, risk management, configuration management, problem resolution, verification, and validation processes).

- Include software development process documentation (e.g. software development plan, software requirements specification, software architecture, software detailed design, software unit testing procedures/reports, software integration testing procedures/reports, and software system testing) and maintenance process documentation (e.g. software maintenance plan). Note: Some documentation may or may not be required per the standards based on software system/module/item risk classification.
- 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.

If software is intended to be used with mobile computing platforms, include information on specific features of mobile platforms demonstrating compliance with SPR 17.3.

Attachment B:

Reference documents

Please note:

- There are NO standards harmonised to 2017/745 at this time
- MedDev guidance documents have scopes that indicate they are applicable to existing Directives.
- Guidance is continuously being updated. 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.

B1 Change Reporting

- NBOG's Best Practice Guide 2014-3, "Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System"

http://www.doks.nbog.eu/Doks/NBOG_BPG_2014_3.pdfhttp://www.team-nb.org//wp-content/uploads/2015/05/nbmeddocuments/Approved_NB-MED_2_5_2_rec_2_november_2008.pdf

B2 Regulatory Guidance Organisations

- EC Commission MEDDEV Guidance – various topics
http://ec.europa.eu/growth/sectors/medical-devices/guidance_en
- International Medical Device Regulators Forum (IMDRF) – various topics, access to all GHTF final documents
<http://www.imdrf.org/>
- NB-MED Guidance – various topics
<http://www.team-nb.org/>
- UK Authorities' MHRA Devices Regulatory Guidance – various topics
<https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety>
- Dutch Authorities' Health and Youth Care Inspectorate, IGJ – Various topics
<https://english.igj.nl/medical-technology>
- GMDN Agency – medical device nomenclature/generic device groups per ISO 15225
www.gmdnagency.com

B3 Specific Topic Guidance

B3.1 Quality management Systems Guidance

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

B3.2 Risk Management Guidance

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

B3.3 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
<http://ec.europa.eu/DocsRoom/documents/17522/attachments/1/translations/en/renditions/pdf>
<http://www.imdrf.org/docs/ghtf/final/sq5/technical-docs/ghtf-sq5-n2r8-2007-clinical-evaluation-070501.pdf>

B3.4 Biological Safety

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

B3.5 PMCF Guidance

- MEDDEV 2.12-2 - Post Market Clinical Follow Up Studies
<http://ec.europa.eu/DocsRoom/documents/10334/attachments/1/translations/en/renditions/pdf>

B3.6 Standards

- EU Harmonised Standards
<http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/>
- BSI Online Standards
<https://bsol.bsigroup.com>
- ISO Online Standards
<http://www.iso.org/iso/home/standards.htm>
- ASTM Standards
<http://www.astm.org/Standards/medical-device-and-implant-standards.html>
<http://www.astm.org/TRACKER/filtrex40.cgi?index.frm>

B3.7 Shelf-Life

- ICH Guidelines Q Series
<http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>

B3.8 Software Guidance

- MEDDEV 2.1/6 - Guidelines on the Qualification and Classification of Stand Alone Software Used in Healthcare Within the Regulatory Framework of Medical Devices

<https://ec.europa.eu/docsroom/documents/17921/attachments/1/translations/en/renditions/pdf>

B3.9 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 to the EMA by a notified body on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device or active implantable medical device

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000523.jsp&mid=WC0b01ac05800267b9

- UK-Authorities' MHRA Guidance note - Devices which incorporate an ancillary medicinal substance

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/650010/Guidance_Note_31_September_2017.doc

Find out more about how BSI
can support your transition
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