QMD Services Quality | Medical | Devices	Title: Guidance for Content and Submission of Technical Documentation		
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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). Subject to classification and conformity assessment route chosen, devices of classification IIa and higher will need their technical documentation assessed by the Notified Body.

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

Medical devices Notified Body QMD Services and medical device manufacturers both have an interest in speeding up the review of Technical Documentation (as part of initial approvals, substantial change approvals, renewal applications etc.) and reducing time to issue certification.

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

- Incomplete Submissions - QMD Services 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, QMD Services proposes the following best practice guidelines.

2. Submission and technical documentation contents

Three things are required for any technical documentation review:

1) Context (i.e. an explanation of what is being requested and why)
2) The technical documentation itself (i.e. objective evidence to demonstrate compliance)
3) Authorisation for QMD Services to carry out the work.

The submission should therefore contain:

2.1. Cover letter

The client's cover letter (email) should contain an executive summary containing at least the following details:

- Certificate # reference(s) (if known)
- The type of review (new product, design change, shelf-life extension, etc.)
- Brief product description, including model numbers involved, etc.
- QMD Services project number (arranged through Client Team) for any other relevant submissions (for example, concurrent applications which may affect the submission)
- An explanation of what has been submitted 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:

Technical Documentation section	*A/NA?*	*Description of evidence submitted; for changes, impact on compliance or rationale for why this section is not affected*

2.2. The technical documentation

For initial approvals under the MDR, a complete submission including all the relevant technical documentation is required (even if the device was previously certified under the MDD or AIMDD).

To assist manufacturers in determining the correct information to provide to QMD Services, a comprehensive checklist of various documents required to be submitted as part of Technical Documentation can be found in the "TD Completeness Check" form from QMD Services. Guidance on each of the items requested in the Completeness Check form can be found in Appendix A of this document. Additional guidance may be found in reference documents listed in Appendix B.

For submissions in the context of certificate scope extensions or substantial change approvals, as far as is practical, submissions should be "stand alone" (i.e. not referring to previous submissions for evidence of compliance). The reason is that the reviewer must be able to 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 QMD Services, 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.)

2.3. Authorisation for the work to be conducted

An approved quote will be required before work can commence. If this is not already in place, please contact your QMD Services Project Leader or QMD Services Client Team (Office@QMDServices.com).

3. Submission Method

- The preferred route for submissions is via the secure QMD Services document upload portal. If you do not have access to the QMD Services document upload portal, please contact your Project Leader 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 QMD Services Project Leader (or Client Team) 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.
- The regulatory requirement for documentation is stipulated in Annex II of the MDR ("*The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex"*)
- We do not accept hard copies of technical documentation.

4. Document Format

4.1. Language

The official language of QMD Services is English, and all submitted Technical Documentation and test results must be in the English language. Please discuss with your QMD Services Project Leader in case this is an issue.

4.2. Electronic File Format

4.2.1. Format and file size limits

- Documents should ideally be provided as paginated, fully searchable bookmarked PDF files (see section 4.2.2 and 4.2.3 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.
- File names should be logical and reflect the information covered within that part. File names should then be cross-referred to in the QMD Services Completeness Checklist.
- Documents should be bookmarked to ensure ease of navigation (see section 4.2.3 below for more information relating to bookmarking).
- It is strongly recommended that one PDF file is submitted for each part specified in the table below. If this is not possible due to file size (Pre-clinical information for example or a stand-alone Clinical Evaluation Report) consider breaking it down into the smallest number of logical sub-sections possible.

Parts	**MDR Cross-references**	**Cross-reference to QMD Services Completeness Check Form**
Part A – Device Description and Specifications including Variants and Accessories	Annex II Section 1	Section 4.2 Part 1
Part B – Information to be supplied by the Manufacturer	Annex II Section 2	Section 4.2 Part 2
Part C – Design and Manufacturing Information	Annex II Section 3	Section 4.2 Part 3
Part D – General Safety and Performance Requirements	Annex II Section 4	Section 4.2 Part 4
Part E – Benefit-Risk Analysis and Risk Management	Annex II Section 5	Section 4.2 Part 5

Part F – Pre-clinical Information (If this section contains substantial amount of information, it is recommended to break it down into logical smaller sub-sections)	Annex II Sections 6.1.a, 6.1.b, 6.2.d, 6.2.f	Section 4.2 Parts 6.1-6.5; 6.11, 6.12, 6.15 – 6.17,
Part G – Clinical Evaluation, PMS and PMCF	Annex II Section 6.1.c, 6.1.d; Annex III	Section 4.2 Parts 6.6, 6.7
Part H – Information related to - Medicinal Substances[1] incorporated in the device - Animal/Human tissue[2] derivatives or cells or other non-viable biological substances - Substances absorbed by or locally dispersed in the human body[3] (for Rule 21 devices)	Annex II Section 6.2.a – 6.2.c	Section 4.2 Parts 6.8 – 6.10
Part I - Sterilisation[4] and Information related to re-usable surgical instruments	Annex II Section 6.2.e	Section 4.2 Parts 6.13, 6.14
Part J – Declaration of Conformity	Annex IV	Section 4.2 Part 6.18
Part K - Specific information for Class III implantable devices, and Class IIb active devices intended to administer or remove medicinal substances as per Rule 12 to determine the need for clinical consultation (i.e. CECP)	MDCG 2019-3	Section 5

[1] Please note: QMD Services is not designated for devices incorporating an ancillary medicinal substance and cannot be assessed by QMD.

[2] Please note: QMD services is not designated for devices that is manufactured by incorporating human tissues, derivatives or cells. However, QMD Services do have in scope devices manufactured by incorporating animal tissues, derivatives or cells.

[3] Please note: QMD Services is not designated for devices that contains substances that are absorbed or locally dispersed in the human body.

[4] Please note: QMD services are designated only for the following methods of sterilisation: radiation, EtO, moist heat (autoclaving), as well as devices manufactured by utilising aseptic processing.

4.2.2. 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

4.2.3. Bookmarks

- Bookmarks are requested to aid in locating major sections of the technical documents. At a minimum, sections in MDR Annex II "Technical Documentation" 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.

4.2.4. Signatures

Signatures are required for any signed document in the file. Signatures can be handled in several ways:

- Documents may be digitally signed.
- Signature pages can be scanned in and inserted into the electronic document.
- All protocols/reports which require approval (as per the legislative requirements & Manufacturer's own procedures and policies), except for the Declaration of Conformity, must have undergone those requisite approvals and be submitted with evidence of those approvals (typically through dated and signed reports, signed protocols, or evidence of approval in an electronic system etc).

5. Submission process

The following is an overview of the submission process:

1) Notify QMD Services that you have an application for review. For new clients, this will generally be via a member of the Client Team (website: QMDServices.com/contact). For existing clients, this will be your Project Leader, or a member of the Client Team.
2) For MDR work, a formal quotation will be required.
3) Once the approved quote (see Section 2.3 above) has been submitted, QMD Services will assign the relevant project number(s) for your review and contact you with those references. We ask that you reference those numbers during document submission via the QMD Services portal or in any email correspondence with QMD Services during the review process.
4) Clients are required to complete an MDR "TD Completeness Check" prior to the start of the detailed review. This ensures all documents needed to initiate the review have been included as part of the technical documentation submission (Appendix A). This ensures much of the first round of questions is not used to ask for key missing information. The requirement for this can be discussed with your Project Leader following quote approval.

5) The conformity assessment of the technical documentation review can begin upon receipt of all required application documentation and QMD Services acceptance of the MDR completeness checklist.
6) QMD Services will then commence the assessment of the technical documentation. Any issues will be discussed with the manufacturer via a maximum of 3 rounds of questions.
7) Providing all issues are satisfactorily resolved, the Project Reviewer makes a recommendation for certification.

6. Additional topics to consider when preparing technical documentation for submission

6.1. Manufacturer personnel support

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

6.2. 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.

6.3. Languages

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

6.4. Certificate scope

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

- Sufficient evidence must be reviewed to support scope change; this may require Quality Management System in additional to the product technical documentation review requested.
- If in doubt, discuss the scope with the QMD Services Project Leader prior to submitting. The Project Leader will coordinate the scope change activities.

6.5. Subcontractors & Suppliers

Are there any changes to subcontractors?

- All critical subcontractors/crucial suppliers must be added to associated EU QMS or Quality Assurance certificate(s) and the Unannounced Audit Visit schedule, so please ensure that your Project Leader and reviewer are aware of any changes. If you are unsure whether a subcontractor/supplier qualify as critical/crucial,

discuss with your Project Leader or with the QMD Services Client Team representative at the time of initial quotation.

- Critical subcontractors/crucial suppliers which do not hold a valid ISO 13485 certificate may require a subcontractor verification audit, depending on the scope of their activities and the verification activities undertaken by the manufacturer. There may be instances where a verification audit is needed, even if they hold ISO 13485 certification from another Notified Body. Please ensure that these details are made clear in the application.

6.6. 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)

6.7. 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. Additional information is required for such devices during the Completeness Check process.
- Some materials (e.g. medicinal substances, human or animal tissues) may require additional regulatory consultations as outlined in MDR Annex IX section 5.2-5.4.
- QMD Services reviewers will still work towards timescales (as indicated in the quotation) for the review process selected, but external consultations may not fall within these timescales. Please discuss with your Project Leader to select the most appropriate review option.

7. APPENDIX A: Information to include in a technical documentation submission

1. Device Description and Specifications Including Variants and Accessories	
1.1 Device Description	
1.1.1 General description including product or trade names, principles of operation, mode of action etc	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.
1.1.2 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.*
1.1.3 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.
1.2 Intended Purpose and Intended Users	
1.2.1 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. ▪ 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[1]. ▪ 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.
1.2.2 Intended users	Identify the intended users of the device (i.e. medical professionals in a specialty, clinical nurses, lay persons, etc.).
1.3 Basic UDI-DI & EMDN code	
1.3.1 Basic UDI-DI and any other relevant UDI related information	The Basic UDI-DI assigned by the manufacturer should be provided. Additional guidance on Basic UDI-DI may be found in the MDCG documents published on the EU Commission website.
1.3.2 EMDN code (previously referred to as CND code, or GMDN)	European Medical Device Nomenclature code (EMDN code; previously referred to as CND code, or GMDN) should be identified (not mandatory for Class III and IIb implantable non-WET devices).
1.4 Devices covered by technical documentation	
1.4.1 List of type, sizes, configurations, variants etc including catalogue numbers covered by the submitted technical documentation	A complete list of product codes should be provided.
1.5 Classification	

[1] Annex XVI is not in scope for QMD Services

1.5.1 Classification of the device including all the applicable rules and relevant rationales	Please indicate the device classification and rationale per MDR Annex VIII. The rationale should address each point of the selected classification rule. If multiple classification rules apply, all should be identified and the strictest rules resulting in the higher classification shall apply. If the device contains multiple components that on their own might be classed differently, please note the higher classification shall apply. If the device is a Well-Established Technology (WET) as per Articles 52.4 and 52.5 of MDR, a rationale supporting the determination of the device as a WET should be included considering any published guidance available on such devices.
1.6 Materials	
1.6.1 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.
1.6.2 Identification of any tissues or cells of human or animal origin that may have been utilized in the manufacture of the device	The submission should clearly indicate whether the device utilizes or is used in conjunction with any human or animal- based products or other non-viable biological substances. Materials which are or include derivatives of human or animal origin should be clearly identified.
1.6.3 Bill of Materials	Submission should include the device Bill of Materials.
1.7 Market History	

1.7.1 Overview of relevant market history of the device (e.g. Date of first making available, Units sold, Previous models, Current and previous regulatory approvals)	All submissions should be accompanied by a market history to enable an understanding of the context of device development.
	▪ If the device is new and has never been marketed by the manufacturer anywhere in the world, please state this explicitly.
	▪ For existing devices:
	  ▪ Ensure that a market history is provided indicating the nature and timing of any changes and that any associated documents (i.e. risk analyses, labelling, clinical evaluation reports, verification / validation data, etc.) account for these changes.
	  ▪ Provide evidence (e.g., QMD Services Reference numbers of previous reviews) to demonstrate that QMD

	Services has been notified of all significant changes (if applicable). ▪ For initial applications under MDR, please confirm whether the device has been previously marketed under the MDD or AIMDD and whether any changes have been made in comparison to the MDD-certified device ▪ Market history should include EU and approvals in other geographies. ▪ If the device is a system, ensure that the number of units sold is broken down by device component and per year Provide Periodic Safety Update Report if applicable (see below)
1.7.2 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.
2. Information Supplied by the Manufacturer	
2.1 User Information	
2.1.1 Device or Product labelling 2.1.2 Sterile packaging labelling 2.1.3 Single unit packaging labelling 2.1.4 Sales packaging labelling 2.1.5 Transport packaging labelling	Medical devices generally use multiple levels of labelling, and it is recognised that not all devices may have the different levels of packaging specified in this section or different terms may be used than those specified here. Legible versions of all applicable levels of labels should be provided (e.g. secondary pack, primary pack) and should be representative of the finished form, showing all included symbols. 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. Please ensure that any specific requirements of relevant harmonized standards or CS are addressed in the labels and information for use.
2.1.6 Instructions for use / Device Operating Manual(s)	Manufacturers must ensure that the information within the IFUs, especially related to intended purpose, indications, contra-indications, and other safety related

	information such as side effects, warnings is aligned with similar information from other sections such as risk management, clinical evaluation etc. IFUs must contain all the information required as per applicable requirements specified within GSPR 23 of MDR Annex I. Manufacturers must as a minimum submit the English version at the time of application. (Manufacturer's processes and procedures for translation into other languages will be audited during QMS audits)
2.1.7 Patient handbook	Some devices incorporate all the information relevant for the patient/user within the IFU itself. Some devices are accompanied by a patient handbook with additional instructions specific to the patient, for example with devices (or parts, components of the devices) that are patient operated. If the device is supplied with a patient handbook, this should be provided.
2.1.8 Physicians handbook	If a separate physicians' handbook is relevant for the device, this should be provided.
2.1.9 Implant card information	If applicable, the implant card and other information per Article 18 of MDR, and any additional information as specified in the MDCG guidance on Implant cards should be included. The location of the implant card within the device or system packaging should be clearly specified. The planned approach for translation of any information not in harmonized symbols should be described if applicable.
2.1.10 Electronic IFU (e-IFU) information (if applicable, and as per (EU) 207/2012)	If electronic IFU will be utilised, ensure compliance has been clearly outlined and evidence included to demonstrate compliance with all relevant aspects of Regulation 207/2012.
2.1.11 Copies of promotional materials (that mention that the device fulfils the requirements of CE marking) including any that make specific claims related to the device	Only marketing literature that mention that the device fulfils the requirements of CE marking or includes the CE mark itself is required to be provided. Supporting evidence should be provided in the relevant pre-clinical and clinical sections to substantiate any claims made in the labelling or marketing literature.
2.1.12 URL of the website where the IFU (and any other labelling information as relevant) will be made available as per Annex I GSPR 23.1	Annex I GSPR 23.1 requires that information related to identification, and safety and performance of the device shall be made available and kept up to date on the manufacturer's website if the manufacturer has a website. The URL of the website where such information will be made available should be included.

3. Design and Manufacturing Information	
3.1 Design Stages	
Summary of design stages applied to the device	MDR Annex II requires the manufacturer to provide "information to allow the design stages applied to the device" to be understood. Include a description of the design phases the device has gone through and the history of any major changes to the design. For previously marketed or "legacy" devices certified under the Directives and applying for MDR certification, it is critical to provide the following: ▪ any changes in the design of the device as approved under the Directives vs the application under MDR ▪ 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.
3.2 Product and Design specifications	
3.2.1 Key product/design specifications of the device (To include component and raw material specifications, including packaging. Specifications should include grade, quality, reference codes, full supplier details as relevant)	Overall, manufacturers should demonstrate that design requirements have been identified in accordance with the intended use, safety and performance requirements, risk assessments, and relevant harmonised and other key standards or CS. The source of design requirements should be indicated. Although compliance to harmonised and other key standards is expected, please be aware that testing beyond that required by the standards may be necessary to demonstrate compliance of your device to the relevant Safety & Performance Requirements. Design requirements should be mapped to the intended use, performance and risks identified for the device. 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.
3.2.2 User requirements	Please clearly identify the user requirements for the device.

3.3 Manufacturing Information	
3.3.1 Overview of the Manufacturing process which also identifies any critical processes involved, including, if relevant, whether sterilisation is conducted on- site or sub-contracted	A detailed overview of the manufacturing processes should be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes As a general principle if any of the information requested in the manufacturing section is not available in English, Manufacturer should either provide translations or provide supplementary summary reports with translations of relevant information/sections or in cases where the information/reports are data heavy (or mainly graphical in nature) with very few words, the Manufacturer may annotate English translations of relevant words within the reports.
3.3.2 Critical process verification protocols/plans 3.3.3 Critical process verification reports	Please identify critical verified processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document. As a part of the initial submission, the Manufacturer should include verification protocols/plans/reports for processes that are verified (as opposed to validated) and are considered critical for the safety and performance of the device. QMD Services Reviewers may request this information for other verified processes (not originally included with the submission) during the review process if required.
3.3.4 Critical process validation protocols/plans 3.3.5 Critical process validation reports	Please identify the critical validated processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document. As a part of the initial submission, Manufacturer should include validation protocols/plans/reports for processes that are validated and are considered critical for the safety and performance of the device. QMD Services Reviewers may request this information for other validated processes (not originally included with the submission) during the review process if required.
3.3.6 Incoming inspections and acceptance criteria & results from a sample batch 3.3.7 In-process inspections and acceptance criteria & results from a sample batch	MDR Annex VII Section 4.5.3, 2nd indent requires that the Notified Body examine the implementation by manufacturers of incoming, in-process and final checks and their results as a part of technical documentation assessment.

3.3.8 Final inspections and acceptance criteria & results from a sample batch	So, technical Documentation should include the following: ▪ Acceptance criteria & results of incoming inspections from a sample batch for the critical raw materials and/or sub-assemblies and/or components ▪ Acceptance criteria & results of in-process inspections from a sample batch for the critical processes identified in sections 3.3.2 and 3.3.3 above ▪ Acceptance criteria & results of final inspections from a sample batch for the finished devices ▪ Identification of party responsible of inspections of subcontracted processes. These processed will be verified during the on-site quality system audit of the manufacturing site.
3.3.9 Installation and Commissioning tests	If the device is required to be installed and/or commission at the user location, provide information on tests to be carried out as a part of the installation and commissioning of the device.
3.4 Sites involved in design and manufacturing activities	
3.4.1 Legal Manufacturer (as per EUDAMED registration)	The application should identify the name and location of the legal manufacturer who is placing the devices on the market. This should be consistent across the device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the legal manufacturer should be identified.
3.4.2 European Representatives	The name and location of the EU Authorised Representative should be identified if required. Only one EU Representative should be identified, and this should be consistent across the device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the EU Authorised Representative should be identified.
3.4.3 Site with Design responsibility	The site(s) responsible for design should be clearly identified. This may be the same as the legal manufacturer or may be another internal or external subcontractor site. If a site other than the legal manufacturer is responsible for design provide copies of their ISO 13485 certificates (see also 3.4.5 below)
3.4.4 Sterilisation subcontractors	The name and address of any critical subcontractors or crucial suppliers should be identified, along with the service or material supplied by each.
3.4.5 Other critical subcontractors and crucial suppliers relevant to the	Provide copies of critical subcontractor ISO 13485 certificates. If a critical subcontractor does not have an ISO 13485 certificate, additional supplier audits may

device(s) including copies of certification held by such entities	need to be arranged (see Section 6.4 of the main document for further information). If you have changed a supplier please include a justification for identifying the new supplier as a Critical Subcontractor. If you remove a supplier, please provide a justification for removing them.
4. General Safety and Performance Requirements (GSPRs)	
4.1 Demonstration of conformity with GSPRs	
4.1.1 GSPR checklist (or in any other format) that meets the requirements of MDR Annex II section 4	MDR Annex II Section 4 requires the technical documentation to include a demonstration of conformity with the applicable General Safety & Performance Requirements (GSPRs) of Annex I, including: ▪ The GSPRs 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 GSPR ▪ 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 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 against the GSPRs to show how compliance with the GSPRs has been achieved.
4.1.2 Standards applied including whether applied in part or full along with the version/date of the standards applied	Usually a list or table. Remember to include the version and date of the standard. Gap analyses may be acceptable in certain instances when the latest version has just been published.
4.1.3 Common Specifications 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). See Appendix B for a link to the most up to date list of harmonised standards. ▪ When identifying applicable standards or CS, indicate if full or partial compliance is being claimed. ▪ Where key standards or CS have not been applied or 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. ▪ Please indicate if there have been any changes to applicable standards or CS since the technical documentation was last reviewed by QMD Services. 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.
4.1.4 Other applicable Regulations & Directives (PPE, Machinery, e-IFU regulation etc)	Please indicate which Regulations and / or Directives apply. If a device is governed by multiple regulations or directives, all applicable regulations / directives should be identified. For example: ▪ If the device is intended to be used in accordance with both the MDR and Regulation (EU) 2016/425 (previously 89/686/EEC) for personal protective equipment, ensure that fulfilment of the relevant basic health and safety requirements of (EU) 2016/425 have been met. ▪ If the device is also machinery (within Article 2a of 2006/42/EC), ensure fulfilment of the relevant basic health and safety requirements of Directive 2006/42/EC Annex I have been met. ▪ If the devices have been impacted by subsequent directives / regulations (e.g. EC 1272/2008, 722/2012, 207/2012) ensure that these are identified, and any new requirements met.

5. Benefit-Risk Analysis and Risk Management	
5.1 Benefit-risk analysis	
5.1.1 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.
5.2 Risk Management	
5.2.1 Risk management procedure	A thorough design and process Risk Management assessment should be conducted for the entire lifecycle of the device (from initial design concept up to and including device disposal). This should be updated (as appropriate) with data from PMS. The analysis must demonstrate that appropriate controls (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.
5.2.2 Risk management plan	Provide the risk management plan associated with the device.
5.2.3 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.
5.2.4 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.
5.2.5 Production/process risk assessment	Provide the documented risk assessment for the production/ manufacturing process aspects of the device.
5.2.6 Clinical/Application/Product risk assessment	Provide the documented risk assessment for the clinical usage/ application aspects of the device.

	Note that for single-use devices, GSPR 23.4(p) requires the risks of re-use to be addressed in a specific section of the risk management and this should be identifiable.
5.2.7 Risk management report	Provide the risk management report associated with the device.
6. Product Verification and Validation	
6.1 Biocompatibility	
6.1.1 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.
6.1.2 Material characterisation test protocols and reports	Include all material characterisation test protocols and reports. 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 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 (GSPR 10.4.5). 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.
6.1.3 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.
6.1.4 Overall biological safety assessment	Biological safety assessments should be undertaken in accordance with ISO 10993-1. See Clause 7 of this standard for guidance with respect to appropriate report content for the overall biological safety assessment. Biological safety assessments should include evidence of compliance for the finished device (including consideration of all materials and all manufacturing steps). It is not enough to simply state that devices have been manufactured from materials of well-established biological safety – an assessment which

	considers the impact of manufacturing and sterilisation processes, intended use, etc. must be provided.
6.1.5 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.
6.2 Electrical safety and electromagnetic compatibility (EMC)	
6.2.1 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. If a subset of devices has been selected for testing and this subset is intended to represent a larger range of devices, provide supporting documentation that demonstrates how the configurations that have been tested can be considered representative of the wider set of devices/configurations.
6.2.2 Electrical safety test reports	
6.2.3 EMC test protocols	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. If a subset of devices has been selected for testing and this subset is intended to represent a larger range of devices, provide supporting documentation that demonstrates how the configurations that have been tested can be considered representative of the wider set of devices/configurations.
6.2.4 EMC test reports	
6.3 Software Verification and Validation	
6.3.1 EN 62304 checklist	Appropriate documentation is required if the medical devices are either stand-alone software or rely upon software. Please provide a checklist against the requirements of EN 62304. If medical device is stand-alone software, guidance for the qualification and classification of the software can be found in MDCG 2019-11 and Classification guidance documents. There should be a rationale for why the software is a medical device and for its classification. If applicable, the software should be broken down into modules, some that have a medical purpose and some that do not. The modules with a medical purpose must comply with the requirements of the 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, maintenance/change management, risk management, configuration management, problem resolution, verification, and validation processes). If software is intended to be used with mobile computing platforms, include information on specific features of mobile platforms demonstrating compliance with GSPR 17.3.
6.3.2 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.*
6.3.3 Software requirements	Include the software requirements specification (SRS). An explanation analysis 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.
6.3.4 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 6.3.3 are allocated to the SOFTWARE ITEMS that comprise the overall SOFTWARE SYSTEM. The following major areas should be addressed in the software architectural design: (1) Internal and external interfaces of the software; (2) Inclusion of any Software of Unknown Provenance (SOUP); (3) Segregation measures that may be necessary for risk control purposes.
6.3.5 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 6.3.4. 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.
6.3.6 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.
6.3.7 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 6.3.8 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.
6.3.8 Software systems testing	Include the software system test protocol(s) and report(s). This testing should demonstrate that each of the software requirements (per 6.3.3) have been verified. It is expected that traceability between the software requirements and the software test cases/test procedures should be established. This testing is typically conducted on the final, compiled SOFTWARE SYSTEM. Input stimuli, expected outcomes, pass/fail criteria, and test procedures should be clearly established in the test documentation. Where test failures or deviations have been encountered, these should be clearly documented and justified in the provided reports. Where automated testing has been used to perform verification activities, include the test scripts and the test log results in the submission documentation.
6.3.9 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.
6.3.10 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.
6.3.11 Cybersecurity documentation	Include documentation related to the design and maintenance of the cybersecurity features of the medical device. Documentation should include the security risk management plan, security risk

	assessment, and verification/validation evidence for the identified security risk controls. Threats and the associated protections needed to ensure the confidentiality, integrity, and availability of the data, function and services of the medical device should be considered. Documentation showing how cybersecurity threats are monitored and responded to as part of the post-market surveillance of the device should also be provided. NOTE: See MDCG 2019-16 Guidance on Cybersecurity for medical devices.
6.4 Stability, including shelf life	
6.4.1 Stability/shelf-life validation protocols (to include both device and packaging performance) 6.4.2 Stability/shelf-life validation results and reports	▪ 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 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 (non-WET) must be reported to QMD Services 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.
6.5 Performance and Safety – Design Verification and Validations	
6.5.1 Design control matrix	A design verification / validation strategy document and / or summary of the outcomes should be provided. Verification / validation results should be provided for each design requirement. If compliance has been demonstrated without testing, an appropriate rationale should be provided For previously marketed or "legacy" devices applying for MDR certification, it is critical to provide an explanation and map of previously conducted testing and outline what testing is relevant to the current version of the device. If historic testing is referenced but a subsequent change was made and only some specifications were re-tested, please explain what test reports have superseded and should be reviewed for each relevant specification.
6.5.2 Design requirements	Please provide the documented design requirements for the device.
6.5.3 Verification and validation plan	Please provide an overall plan for design verification and validation, if applicable.
6.5.4 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: ▪ 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.
6.5.5 Validation protocols and results	Please provide the protocols and results for design validation studies. See also 6.5.4 for guidance on appropriate contents and rationales.
6.5.6 Usability study protocols and results	Please provide the protocols and results for usability studies. See also 6.5.4 for guidance on appropriate contents and rationales.
6.5.7 Evidence to support the device lifetime in use	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".
6.5.8 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.
6.6 Clinical Evaluation	
6.6.1 Clinical development strategy	Please explain the clinical development strategy for the device.
6.6.2 Clinical development plan	See MDR Annex XIV, Part A, 1 (a) final indent.
6.6.3 Clinical evaluation plan	Please provide the clinical evaluation plan documented and used for the device.
6.6.4 Clinical evaluation report	Clinical evaluations are required for all medical devices. 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). In the context of equivalence, Manufacturers should also include any additional information necessary to show compliance with the requirements of MDR Article 61.5 for implantable devices and Class III devices. If the device is a system with multiple components, the clinical evaluation must consider all the components of the device. Similarly, the clinical evaluation must give due consideration to the accessories associated with the device.
6.6.5 CVs of the relevant personnel associated with the Clinical evaluation report to establish appropriate competence	A justification should be provided (with appropriate evidence) to substantiate the qualifications of individual(s) conducting / approving the clinical evaluation.
6.6.6 Clinical investigation protocols	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 GSPRs ▪ The device is demonstrated to be equivalent to an already marketed device of another manufacturer and a contract is in place explicitly allowing ongoing access to that manufacturer's technical documentation ▪ For listed device types where the clinical evaluation is based on sufficient data and in compliance with relevant CS ▪ The device had been lawfully placed on the market or put into service per Directives 90/385/EEC or 93/42/EEC, 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 Clinical investigation of medical devices for human subjects - Good clinical practice If a pre-market clinical investigation has been conducted, please ensure: ▪ appropriate documentation (clinical investigation plan, 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.
6.6.7 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 6.6.6
6.6.8 Statistical analysis plans	A clear description must be provided of the statistical tools, techniques, analyses used in the design and conduct of clinical investigations, and analysis of clinical data within the overall clinical evaluation.
6.6.9 Copies of literature articles	A copy of all literature articles selected and analysed within the clinical evaluation report should be included in the technical documentation.
6.6.10 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 clearly and understandable to the intended user and patient (if relevant) and should contain all the elements listed in MDR Article 32, Sec 2.

	▪ Please consult current available guidance for SSCP content and format as per MDCG 2019-9. ▪ A draft SSCP in English is acceptable at the time of initial submission. ▪ Once the SSCP has been finalised based on QMD Services review, Manufacturers should submit the final version of the English SSCP, which is in pdf format and is printable, searchable before a certificate recommendation can be made. ▪ The SSCP should be updated annually (as per Article 61), if indicated, over the lifetime of the device as needed, and updates should be defined in the Post-Market Surveillance Plan. For Class IIa implantable and Class IIb implantable WET (Well-Established Technologies) devices, MDR allows NBs to choose representative devices from each device category or generic device group respectively for the assessment of technical documentation. The SSCPs for such devices chosen as the representative samples will be validated by the NB as part of the technical documentation assessment for those devices. The MDCG 2019-9 requires that NBs also upload the unvalidated SSCPs of the devices that were not chosen as representative devices (but are part of the same device categories or generic device groups) to EUDAMED. Hence Manufacturers may submit these unvalidated SSCPs at any time during the certification process to QMD Services, but before a QMD Services Project Leader prepares and makes a recommendation for certification based on the completion of all the required conformity assessments (including technical documentation assessment) for the relevant device categories or generic device groups. (The MDCG guidance on SSCPs, MDCG 2019-9, also includes several requirements related to languages, translations of SSCPs depending on the Member State requirements related to languages and the availability of translated SSCPs on EUDAMED prior to placing affected devices on the market within these Member States. Manufacturer's processes/procedures related to making the translated SSCPs available to QMD Services (for the NB to upload these to EUDAMED) and ensuring that they are available on EUDAMED prior to placing the devices on the market within these Member

	States will be audited as part of the QMD Services QMS audits)
6.7 Post Market Surveillance & Post Market Clinical Follow-up	
6.7.1 Post Market Surveillance data (Market History, worldwide and EU sales volumes, Complaints data and trend analyses; Vigilance data and trend analyses; data from other PMS sources)	Please provide sales, complaints and vigilance data for the last 5 years for your device, ▪ Sales and complaints data should include sales outside of the EU. A breakdown should be provided to enable evaluation of sales and complaints by region. ▪ Complaints data should be evaluated rather than just listed. For example, why is the complaints rate considered acceptable? Have any trends been analysed and noted, or corrective actions taken? What is the status of these actions? Has a comparison of PMS data been made to the expected occurrence in the risk assessment? Full details of vigilance issues should be provided, including the status of any Field Safety Corrective Actions or Notices, the associated CAPAs and patient outcomes. This data should include FSCA or FSN outside the EU, if related to a device which is sold in the EU. ▪ Ensure that the PMS data submitted at the time of the submission is up to date.
6.7.2 Post market surveillance plan	A Post-Market Surveillance Plan (PMS Plan) commensurate with the product risk, lifetime, and available clinical data should be provided for each device / device family. ▪ 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.
6.7.3 Periodic Safety Update Reports (if available)	For Class III, IIb, and IIa devices, manufacturers must prepare a periodic safety update report ("PSUR") for each device or group of devices summarising results and conclusions of post-market surveillance data analysis as a result of the PMS plan described above. The PSUR should contain all the elements outlined in MDR Article 86 and any applicable MDCG guidance documents. Any PSURs the manufacturers may have issued by the time of submission must be included.
6.7.4 Post market clinical follow-up plan & protocols	Please provide a PMCF plan including all necessary elements outlined per Part B of MDR Annex XIV and any applicable MDCG guidance documents. If the PMCF plan includes a PMCF study, include the study protocol.
6.7.5 Post market clinical follow-up reports	Include any information and reports from PMCF activities previously carried out. This should clearly identify the PMCF study, which products are included and the applicable indication of use. In cases with multiple products and studies a table is preferable. The Notified Body may be required to periodically review results from ongoing or completed PMCF studies following CE mark certification, including a specialised clinical evaluator in some cases.
6.9 Devices utilising tissue and cells of human[1] or animal origin or their derivatives or other non-viable biological substances (as per GSPR 13.3)	
6.9.1 Information on the nature of the animal starting tissue, animal species and geographical nature	The submission should clearly indicate whether the device utilises or contains any human or animal- based products or other non-viable biological substances. If the device is a system and includes multiple components, then identify the components which incorporate these substances. Manufacturing subcontractors should be consulted if appropriate to establish if any such substances are used during manufacture, even if they do not feature in the final device (e.g., lubricants or mould release agents which may use animal derived substances). The manufacturer should request evidence of compliance to ISO 22442 or EU 722/2012 or for any applicable exclusions (e.g., tallow species and processing method
6.9.2 Animal tissue (or their derivatives) related risk assessment (either stand-alone or as a part of the risk management section)	
6.9.3 Justification for the use of animal tissues or their derivatives	

[1] Please note: QMD Services is not designated for the assessment of human derivatives, and cannot assess these types of devices

	utilised) from the subcontractor. If in doubt, speak with your Project Leader before submitting a dossier.
6.9.4 Information to establish compliance with EN ISO 22442-1	Devices which incorporate 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). Manufacturers must ensure that the labels and IFU submitted in Section 2 above include relevant information related to the animal tissues or cells or derivatives utilised or contained in the device as per GSPR 23.2 and GSPR 23.4.s.
6.9.5 Information to establish compliance with EN ISO 22442-2	
6.9.6 Information to establish compliance with EN ISO 22442-3	
6.9.7 Evidence to support compliance with GSPR 13.3 for devices utilising non-viable biological substances	
6.11 Devices containing CMR or endocrine-disrupting substances referred to in GSPR 10.4.1 of Annex I of MDR	
6.11.1 Data related to the estimation of potential patient or user exposure to the substances	GSPRs 10.4.1 - 10.4.5 describe specific requirements for devices that contain substances which are carcinogenic, mutagenic or toxic to reproduction and substances having endocrine-disrupting properties. 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. 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.
6.11.2 Information/data on analysis of possible alternative substances, materials or designs	
6.11.3 Rationale for the presence of CMR and/or endocrine-disrupting substances above 0.1% (w/w) considering the alternatives	
6.11.4 Labelling indicating the presence of CMR and/or endocrine-disrupting substances above 0.1% (w/w)	
6.12 Packaging and Transit (Transport) testing	
6.12.1 Packaging drawings and/or configurations	A complete packaging BoM and diagrams should be provided to illustrate how each device is packaged.
6.12.2 Packaging validation	Please provide the protocols and reports for packaging validation. For sterile protocols devices, this must include the validations carried out towards establishing the sterile barrier. 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
6.12.3 Packaging validation reports	

	standards are not used, alternate methods must be duly justified in terms of their suitability and state of the art. ▪ If all packaging configurations / device combinations have not been tested, a rationale based on worst case (i.e. heaviest and lightest devices, sharp or pointy edges, etc.) should be provided. ▪ Changes to packaging could potentially be considered as significant changes. For Class III devices and Class IIb implantable devices, these must be reported to QMD Services for review and certificate re-issue.
6.12.4 Transit/transport testing protocols 6.12.5 Transit/transport testing reports	Please provide protocols and reports for any transit/transportation testing conducted on the device to establish transit endurance and maintenance of the sterile barrier in case of sterile devices.
6.13 Sterilisation	

6.13.1 Sterilisation Validation protocol
6.13.2 Sterilisation Validation results and reports
	Sterilisation is assessed by a PR that is coded for the specific type of sterilisation method within the QMD Scope of designation (moist heat, EtO, radiation) or alternatively by aseptic processing.
	▪ 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:
	  ▪ 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
6.14 Reusable surgical instruments	
6.14.1 Cleaning, Disinfectant, Sterilisation Validation Protocols in support of the instructions within IFU	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 protocol and report for the sterilisation parameters listed in the IFU ▪ Validation protocol and report for the cleaning parameters listing in the IFU
6.14.2 Cleaning, Disinfectant, Sterilisation Validation reports and data in support of the instructions within IFU	
6.15 Devices with a measuring or diagnostic function	
6.15.1 Protocols 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, precision, calibration etc Refer to MEDDEV 2.1/5 for guidance on criteria that qualify a device as having a measuring function.
6.15.2 Reports for tests associated with establishing the device limits of accuracy, precision, calibration etc	
6.16 Devices intended to be connected to other devices to operate as intended	

6.16.1 Protocols for tests associated with establishing the safety and performance of the device and the combination while connected to other devices and their interoperability	If the device is intended to be connected to other devices to operate as intended, include test protocols and reports that establish the safety and performance of the combination of devices including addressing their interoperability and any usability elements.
6.16.2 Reports for tests associated with establishing the safety and performance of device and the combination while connected to other devices and their interoperability	
6.17 Magnetic resonance imaging safety of implants	
6.17.1 MRI safety test protocol 6.17.2 MRI safety test results 6.17.3 MRI safety labelling	MR safety of implants must be established following relevant harmonised and/or international standards such as ASTM standards. Include test protocols, reports and associated labelling (if not already included in the labelling section above) ▪ MRI safety characterisation should be undertaken according to the ASTM standards or ISO/TS 10974:2018 as appropriate depending on the nature and classification of the device. This information must be related back to the safety and performance requirements of the device while allowing a clinically acceptable MRI to be performed. If this Technical Specification is not used as guidance, justification should be provided for the validity of assessment methods and conclusions. ▪ The guidelines of the Design Verification section of this document should generally be applied during the MR safety assessment. ▪ If RF test results are considered representative of a group of devices (i.e. worst-case devices or comparative devices) extensive justification should be provided, typically including objective evidence. ▪ An MRI safety assessment summary should be provided, with evidence that hazards associated with each clause of ISO/TS 10974:2018 have been assessed and appropriately mitigated if necessary. ▪ Labelling/IFU related to MRI safety should be provided. Details of any assumptions and configurations used in the assessment should be disclosed in the labelling/IFU. It is important that the labelling/IFU clearly

	communicates which scenarios and configurations have been shown to be safe and which are untested. ▪ Evidence that any safety critical labelling/IFU is clear and correct and can be accurately interpreted by the typical user (MR technologists and/or radiologists), should be provided. ▪ Assessment of the clinical benefit of allowing patients to get MRI vs. the residual risk
6.18 Declaration of Conformity	
6.18.1 Draft Declaration of conformity provided as per Annex IV of MDR	The EU Declaration of Conformity should include all the information listed in MDR Annex IV.

8. APPENDIX B: Reference Documents

(NOTE: Guidance related to MDR issued by MDCG and other entities evolve 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)

Medical Device Regulation Guidance:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

Other Guidance bodies:

https://www.nbog.eu/nbog-documents/

http://www.imdrf.org/documents/documents.asp

http://www.team-nb.org/

https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices

https://www.camd-europe.eu/resources/

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