



Medical Devices Regulation

Technical Documentation Submissions Lessons Learnt

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5th May 2021

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By Royal Charter



Your Speakers Today

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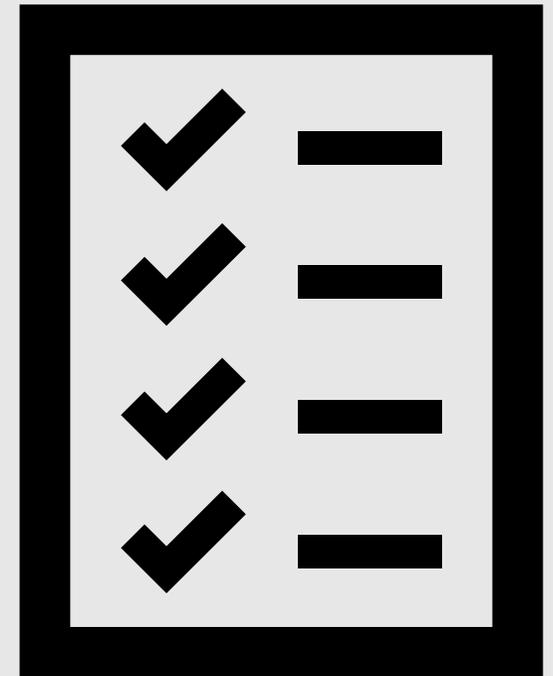
The most common reasons for delays in technical documentation reviews are:

- **Incomplete Submissions** - all the information needed for the review not provided
- **Poor structuring of Technical Documentation** – information present but difficult to locate.



Agenda

1. MDR Technical Documentation Review Process
2. Common Gaps/Questions from MDR Technical Reviews
3. Improving Technical Documentation Submissions
4. Questions



How confident are you that you understand the MDR Requirements in relation to Technical Documentation Submissions?

- a) Very Confident
- b) Slightly Confident
- c) Enough to Survive
- d) Don't have a clue!



MDR Technical Documentation Review Process



MDR Annex II - Technical Documentation (TD)

L 117/108

EN

Official Journal of the European Union

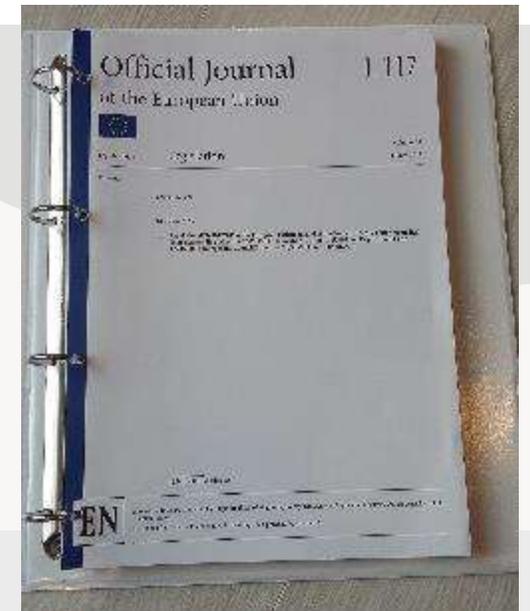
5.5.2017

ANNEX II

TECHNICAL DOCUMENTATION

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.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES
2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER
3. DESIGN AND MANUFACTURING INFORMATION
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT
6. PRODUCT VERIFICATION AND VALIDATION



Annex II Technical Documentation

1. Device Description
2. Information to be supplied by the manufacturer
3. Design and Manufacturing Information
4. General Safety and Performance Requirements
5. Benefit-Risk analysis and risk management
6. Product verification and validation

Annex III Technical Documentation on Post- Market Surveillance

- Post-Market Surveillance (PMS) Plan
- Post-Market Clinical Follow-Up (PMCF) Plan
- Periodic Safety Update Report (PSUR)

Annex XIV – Clinical
Evaluation and Post-Market
Clinical Follow-Up

MDR Technical Documentation – Best Practice

- BSI provides this guide.
- A complete and well-organised technical documentation file decreases time and cost of the review.
- Searchable, bookmarked PDF files
- The technical documentation should be available in full in accordance with Annex II.



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<https://www.bsigroup.com/globalassets/meddev/localfiles/de-de/documents/bsi-md-mdr-best-practice-documentation-submissions-en-gb.pdf>

MDR Technical Documentation Completeness Check

MDR Technical Documentation Completeness Check

3 Supplemental Guidance

Guidance is available from BSI on the best practices in relation to preparation of Technical Documentation from the following link: <https://www.bsigroup.com/globalassets/meddev/localfiles/en-qb/documents/bsi-md-mdr-best-practice-documentation-submissions-en-qb.pdf>

4 Technical Documentation Completeness Checklist

4.1 Client Details

Manufacturer	
Single Registration Number (SRN)	
Name of the device(s) the Technical Documentation is associated with	
Basic UDI-DIs covered	
Impacted BSI certificates (if known)	
Date of submission to BSI	

4.2 Technical Documentation Checklist

Section Title	Item	Location of the requested information; Mark as "N/A" if not applicable and provide a brief justification	BSI Completeness Check (To be completed by BSI)
Overview	Cover letter		<input type="checkbox"/> YES <input type="checkbox"/> NO
	MDF4900 – BSI Change Notification Form		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	Document index:		<input type="checkbox"/> YES <input type="checkbox"/> NO
	Top level (or summary) Technical Documentation (STED) file		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
BSI Comments - Overview			
1. Device Description and Specifications Including Variants and Accessories			

Section Title	Item	Location of the requested information; Mark as "N/A" if not applicable and provide a brief justification	BSI Completeness Check (To be completed by BSI)
1.1 Device Description	1.1.1 General description including product or trade names, principles of operation, mode of action etc		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	1.1.2 Accessories included		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	1.1.3 Accessories not included but necessary for use		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
1.2 Intended Purpose and Intended Users	1.2.1 Intended purpose including any clinical claims		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	1.2.2 Intended users		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
1.3 Basic UDI-DI & EMDN code	1.3.1 Basic UDI-DI and any other relevant UDI related information		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	1.3.2 EMDN code (previously referred to as CND code)		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
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		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
1.5 Classification	1.5.1 Classification of the device including all the applicable rules and relevant rationales		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
1.6 Materials	1.6.1 Description and identification of key materials incorporated into the device		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification

Make a full and thorough MDR submission

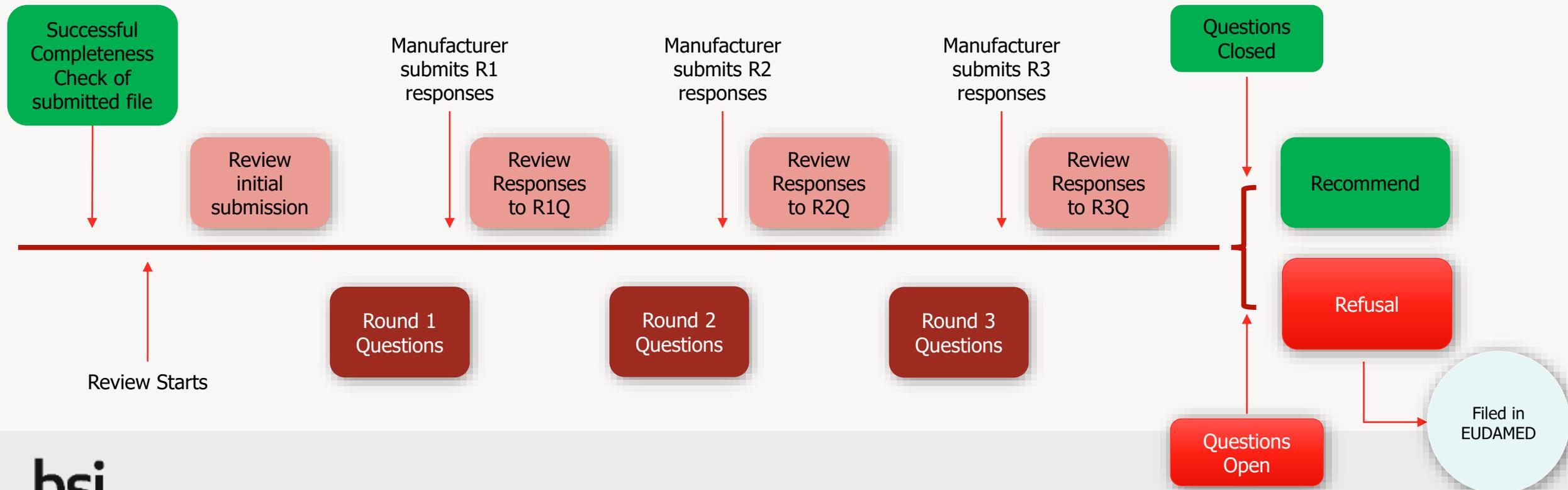
- Completeness Check prior to formal TD review

~~".....We thought we would send you the top-level documents, and then follow up with more as you need them." - Manufacturer~~

Section Title	Item	Location of the requested information; Mark as "N/A" if not applicable and provide a brief justification	BSI Completeness Check (To be completed by BSI)
3.4 Sites involved in design and manufacturing activities	3.4.1 Legal Manufacturer (as per EUDAMED registration)	Section 1.2 of ABC-XYZ-035 (Page 5)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	3.4.2 European Representatives	Section 1.3 of ABC-XYZ-035 (page 5)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	3.4.3 Site with Design responsibility	Section 4.3 of ABC-XYZ-035 (page 16)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	3.4.4 Sterilisation subcontractors	Section 4.3 of ABC-XYZ-035 (Page 17)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification
	3.4.5 Other critical subcontractors and crucial suppliers relevant to the device(s) including any copies of certification held by such entities	Section 4.3 of ABC-XYZ-035 (Page 17)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> N/A with justification No critical subcontractors listed
BSI Comments – Section 3	Inclusion of requested information confirmed except no critical subcontractors listed . Please confirm if there any other critical subcontractors and crucial suppliers relevant to the device? If yes, please provide copies of certification held by such entities.		

MDR TD Review Limitations – some specifics

- 3 rounds of questions
- MDR Annex VII section 4.5.1 specify rationale for time limits for completion of conformity assessment activities
- BSI rationale based on rounds of questions rather than a time limit



MDR TD Assessment – Timing and Limitations



Completeness
Check

Ensuring all documentation is present and generally complete at a glance – not a detailed technical assessment



Three rounds

BSI will be required to reject applications if gaps cannot be addressed in three rounds of questions

In those cases, Manufacturer will be required to resubmit an amended application

Technical Documentation Assessment – MDCG 2019-13

5.1. Depth of the assessment

The depth and extent of the technical documentation assessment of Class IIa / IIb and Class B / Class C devices will be the same as the depth of assessment carried out for Class III and Class IIb implantable and Class D devices.

This means that the technical documentation of a device shall be assessed against all General Safety and Performance Requirements (Annex I) and requirements of Annex II and III. Records of the assessment shall be prepared which allow a third party to understand the functionality of the device and all aspects of the assessment including judgements made by the assessor.

It should be taken into account that every device (i.e. Basic UDI-DI) might include different variants, models or sizes. In that case, the review of the technical documentation will also include the assessment of how the differences among these have been addressed in the technical documentation and whether all of them are in line with the relevant requirements.

Depth and extent of TD assessment to be same irrespective of device classification



TD assessment durations determined by device type (MDA/MDN codes) and complexity rather than device classification;

- Characteristics such as presence of animal tissues, nanomaterials (MDS codes) increase the assessment durations

It is important to follow the EU Guidance Documents because...

- relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,
- evaluate and verify a manufacturer's compliance with relevant Annexes.

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

MDR, IVDR - Annex VII Section 4.5.1

EU MDCG Guidance Documents

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

Topic Headings Include:

- UDI
- EUDAMED
- European Medical Device Nomenclature (EMDN)
- Notified Bodies
- Clinical Investigation and Evaluation
- New Technologies
- Other Topics
- Commission guidance Documents
- Other Guidance Documents

Medical Devices - Sector

Home All topics Overview Current Directives New Regulations

Guidance - MDCG endorsed documents

The European Commission provides a range of guidance documents to assist stakeholders in implementing the medical devices regulations.

Legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) in accordance with Article 105 of Regulation 745/2017, pursue the objective of ensuring uniform application of the relevant provisions of the regulations within the EU.

❖ **MDCG work in progress**
Ongoing guidance documents

❖ **UDI**

Reference	Title	Publication
MDCG 2018-3 Rev.1	Guidance on UDI for systems and procedure packs	June 2020
MDCG 2018-1 v3	Guidance on basic UDI-DI and changes to UDI-DI	March 2020

MDCG Guidances, EUDAMED

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en
https://ec.europa.eu/health/md_eudamed/overview_en

Guidance - MDCG endorsed documents

The European Commission provides a range of guidance documents to assist manufacturers in complying with the new regulations.

Legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) under the direction of ensuring uniform application of the new regulations.

MDCG work in progress
 Ongoing guidance documents

UDI

Reference	Title	Publication
MDCG 2019-6 Rev 1	Guidance on UDI for systems and procedure packs	July 2019
MDCG 2019-7 v3	Guidance on UDI (2) and changes to UDI (1)	May 2020
MDCG 2019-8	MDCG guiding principles for issuing written rules on UDI (2)	May 2020
MDCG 2019-2	Guidance on application of UDI rules to device part of accessories under IEC 60601 and IEC 60601-1	April 2019
MDCG 2019-3	Guidance on application of UDI rules to device part of accessories under IEC 60601 and IEC 60601-1	April 2019
MDCG 2019-4	Guidance on application of UDI rules to device part of accessories under IEC 60601 and IEC 60601-1	April 2019
MDCG 2019-5	Guidance on application of UDI rules to device part of accessories under IEC 60601 and IEC 60601-1	April 2019
MDCG 2019-6	Guidance on application of UDI rules to device part of accessories under IEC 60601 and IEC 60601-1	April 2019
MDCG 2019-7	Guidance on application of UDI rules to device part of accessories under IEC 60601 and IEC 60601-1	April 2019

EUDAMED

Reference	Title	Publication
MDCG 2020-19	MDCG Position Paper on the use of the EUDAMED data request module and of the Single Registration Number (SRN) in the MDR	April 2020
MDCG 2019-9	Timeline for registration of device data elements in EUDAMED	March 2020
MDCG 2019-10	Regulation of legacy device data in EUDAMED	December 2019

European Medical Device Nomenclature (EMDN)

The EMDN - The nomenclature of use in EUDAMED

The EMDN - The nomenclature of use in EUDAMED

Notified bodies

Reference	Title	Publication
MDCG 2020-14	Guidance on notified bodies on the use of MDR/IVDR multi reports to support the submission of data under the Medical Device Regulation (MDR)/in vitro Diagnostic Regulation (IVDR)	July 2020
MDCG 2020-10	Guidance on transitional provisions for consultations of authorities concerning a substance which may be considered a medicinal product when used in combination with a device, as well as an active ingredient used in combination with a device	April 2020
MDCG 2020-11	Guidance on the removal of designation and marketing of notified bodies (NBDs) and (NBDs) to be replaced	April 2020

Clinical investigation and evaluation

Reference	Title	Publication
MDCG 2020-13 Rev 1	Clinical evaluation assessment report template	July 2020
MDCG 2020-19 Rev 1	Guidance on safety reporting in clinical investigations	May 2020
MDCG 2020-18	Algorithm: Clinical investigation summary safety report form	May 2020
MDCG 2020-8	Guidance on PFCF evaluation report template	April 2020
MDCG 2020-7	Guidance on PFCF report template	April 2020
MDCG 2020-6	Guidance on sufficient safety evidence for legacy devices	April 2020
MDCG 2020-5	Guidance on clinical evaluation - Equivalence	April 2020
MDCG 2019-4	Summary of safety and clinical performance	August 2019

New technologies

Reference	Title	Publication
MDCG 2020-1	Guidance on clinical evaluation (MCE) / Performance evaluation (PE) of medical device software	March 2020
MDCG 2020-11	Qualification and validation of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2019
MDCG 2019-18 Rev 1	Guidance on cybersecurity for medical devices	December 2019

Other topics

Reference	Title	Publication
MDCG 2020-4	Regulatory requirements for venturers and related accessories	April 2020
MDCG 2020-3 Rev 1	Interpretation of article 14(2)	April 2020
MDCG 2020-1 Rev 1	Class I transitional provisions under Article 10(3) and 11(1) (MDE)	March 2020
MDCG 2019-12 v2	Guidance document issued based on the application of Article 10(3) Regulation (EU) 2017/745 on medical devices	March 2020
MDCG 2019-13 Rev 1	Guidance notes for manufacturers of class I medical devices	December 2019
MDCG 2019-7	Guidance on article 11 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a person responsible for regulatory compliance (PRRC)	June 2019

Commission guidance documents

Reference	Title	Publication
COM(2020) 10	Conformity assessment procedures for protective equipment	July 2020
COM(2020) 10	How to verify that medical devices and personal protective equipment can be safely stored in the EU market and that purchased and used - also in the COVID-19 context	May 2020
COM(2020) 10	Guidance on regulatory requirements for machine tools	June 2020
COM(2020) 10	Guidance on machine tools, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context	April 2020
COM(2020) 10	Conformity assessment procedures for CE marking and CE marked products to be used in a medical context for COVID-19	April 2020

Medical Devices - EUDAMED

All topics Overview

Overview

EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

The new Regulations contain important improvements including a much larger EUDAMED database than the one that currently exists under the Medical Devices Directives (Eudamed2).

EUDAMED will improve transparency and coordination of information regarding medical devices available on the EU market.

The system will be multipurpose: it will function as a registration system, a consultative system, a notification system and a dissemination system (open to the public) and will be interoperable.

EUDAMED is structured around 5 interconnected modules and a public website:

- Actors registration
- UDI/Device registration
- Notified Bodies and Certificates
- Clinical investigations and performance studies
- Vigilance and post-market surveillance
- Market surveillance

What is the state of play of the implementation of EUDAMED?

- The development and implementation of EUDAMED is a high priority for the Commission
- The Commission, in agreement with the Medical Device Coordination Group (MDCG), is going to make available the different modules on a gradual basis as soon as they are functional
- The module on Actor registration will be the first module made available. Deployment of the module is planned for December 2020
- The module on UDI/device registration (second module) and the module on Certificates and Notified Bodies (third module) will become available by May 2021. Afterwards, the remaining modules will be deployed as soon as they are functional

Functional specifications

The Eudamed functional specifications (v4.1) have been public since 7 February 2019. These functional specifications might be subject to possible changes as some issues are still under discussion.

MDR/IVDR UDI and device

Overview of the MDR UDI and device data sets and IVDR UDI and device data sets to provide for their registration in EUDAMED

EUDAMED UDI device data dictionary - This document clarifies the data that you should provide to EUDAMED for the UDI device registration module

How often are manufacturers checking for changed documents and the impact on processes?

Get notified of updates to EU Guidance Documents

https://ec.europa.eu/health/md_sector/overview_en

❖ Newsletter

- Subscribe to the Medical Devices newsletter

Have you already submitted a file for MDR technical documentation review to your Notified Body ?

- a) Yes
- b) No, but ready to submit
- c) No, we're not ready yet



POLL

MDR Technical Documentation Lessons Learned



Technical Documentation – Overall Feedback

- Generally, new MDR requirements are being clearly addressed
- Some areas continue to evolve with guidance being published and further experience being gained
- “Legacy” device challenges
 - Stand-alone new application file required; not “gap analysis to MDR”
 - Clear organization of files and data
 - Large numbers of reports with no explanation or map will slow review time
 - Consider testing map or summary tables
 - Rationales for applicability of any leveraged tests
 - Justifications needed when historical testing performed does not meet current standards (e.g. ISO 10993 and others)

Technical Documentation – General Feedback

- ✓ Know your audience – provide context and evidence
- ✓ All relevant reports must be provided - it is not acceptable to reference or leverage tests from the same device or another device that were “previously reviewed by BSI under MDD” without providing these test protocols/reports
- ✓ Avoid chain referencing
- ✓ Review file fully before submitting



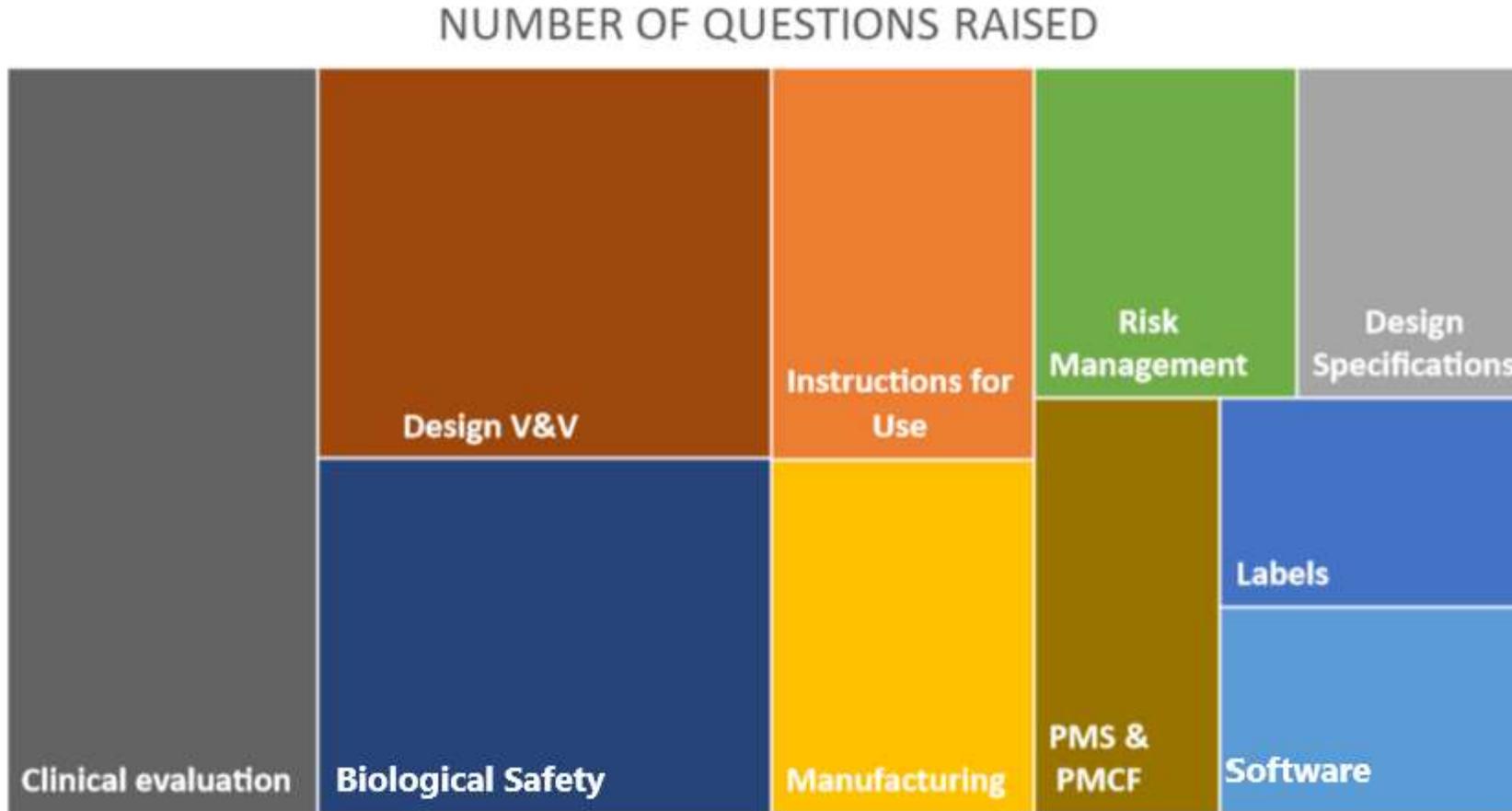
What have you found most challenging when preparing your technical documentation for submission to your Notified Body?

- a) Biological Evaluation
- b) Clinical evaluation
- c) Design V&V
- d) Design and Manufacturing Information
- e) None of the above



POLL

Technical Documentation – Questions Raised



These are early trends and may change with time and more experience

For “Legacy” MDD Devices – Tell the Story

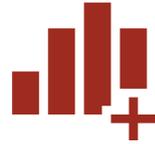


Devices with a long history under MDD may have a history of device changes and/or company acquisitions

While each change was likely reviewed individually under MDD, MDR is a new stand-alone application with no grandfathering and **all testing must be presented and explained clearly**



If it is **not clear what testing was performed on what version, or what other testing was leveraged / justified over time**, please clearly outline this to avoid questions



Please do not present a **“stack” of design verification/validation reports with no context or explanation** – this will increase the review time and cost



Similarly - if it is **not clear which clinical data was obtained on what historic version of the device**, please clearly outline this and justify applicability (equivalence) if the device has changed

Refer to BSI Best Practice Guidelines for additional guidance

Design V & V – Some common gaps

A clear trace matrix between specifications and relevant reports / sections can reduce review time significantly

Design requirements not fully verified/validated

Missing protocols, reports – provide all referenced in design input/output matrix

Unclear organization of tests for legacy devices

Unclear / hidden rationales for leveraged tests

Evidence of performance over lifetime of device not demonstrated

Test acceptance criteria not met – No justifications for accepting results

Sample sizes, selection criteria and preparation unclear

& many more....

Many apply to packaging tests also

Design V&V Roadmap – Acme Catheter 2.0



Specification	Acceptance Criteria	Testing Protocol/Report	Sample Tested	Justification for Sample Tested	Location in TD
1.01 – Tensile Strength of Tip	>5N	P/R2013-06 – New Tip Design t=0 P/R2013-08 – New Tip Design t=24	Acme Catheter 2.0	Same subject device under application	Appendix 83 t=0 Appendix 84 t=24
1.02 – Tensile Strength of Hub	>8N	P/R2011-03 – Acme t=0 P/R2011-05 – Acme t=24	Acme Catheter 1.0	Hub same as current 2.0 version under application; specification not impacted by tip change to 2.0	Appendix 86 t=0 Appendix 87 t=24
1.03 – Liquid Leakage	No leaks at <30 psi	P/R2011-03 – Acme t=0 P/R2011-05 – Acme t=24	Acme Catheter 1.0	Shaft same as current 2.0 version under application; specification not impacted by tip change to 2.0	Appendix 86 t=0 Appendix 87 t=24
5.11 – Pouch Peel Strength	> 1N/in	P/R2009-02 – CathBot t=0 P/R2009-05 – CathBot t=36	CathBot RX	Pouch and tray design identical to Acme 2.0 and mass of CathBot worst case; same acceptance criteria and testing method; shelf life greater than subject device	Appendix 88 t=0 Appendix 89 t=36

Other content to consider: Location of protocols; Sample size and justification; standard version used; rationale for any deviation to test methods or difference in acceptance criteria



Application of Standards

- No standards are yet harmonized to 2017/745 (MDR)
- List of standards to be harmonized is published but this has not yet been completed
- The most current standards are therefore considered state of the art e.g. ISO 14971:2019
- Present a clear gap analysis if older version of standards used
 - For tests, address whether current standards are considered met, conclusion why additional testing was not required
 - Often seeing different versions in a “claimed standards” list compared to test reports, with no gap analysis or explanation – present this proactively
- MDCG 2021-5, Guidance on standardisation for medical devices, April 2021

Medical Devices

Medical Device Coordination Group Document

MDCG 2021-5

MDCG 2021-5

Guidance on standardisation for medical devices

April 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Clearly present Annex I / GSPR Compliance

Have applicable and non-applicable requirements been clearly noted with appropriate and relevant rationales?
It may be that certain sub-parts apply while others do not – consider the need for addressing applicability individually

Has the “precise identity of the controlled documents offering evidence of conformity” (Annex II, Section 4.d) been identified for each including document location?
e.g. “Design Verification Testing, Tech Doc Section 8” is not precise and is not fully applicable to each GSPR where it might be listed.

Possible Questions

Have applied standards, Common Specifications, and guidances been identified, along with extent of compliance and version / year claimed?
Have all other applicable Directives & Regulations (Animal Tissue, Machinery, PPE, eIFU, etc.) been identified?

If cited standards are in a referenced list and not directly in the GSPR Checklist, is the list of claimed standards traceable?
Are the cited standard versions consistent with those listed in the test reports or has a gap analysis been presented?

Biological Safety – Common Issues

No overall biocompatibility assessment of the current version of the device under application

- Test reports for each iterative change over the years, without an overall explanation / assessment of current device
- Make clear the relevance of each test and how the subject device was considered as a new application
- Do not submit every biocompatibility test in a DHF with no explanations
- Overall biological safety assessment by qualified individual/team

Context of tests not clear

- Rationales for any tests leveraged comparing device specifics
- Rationale for any device attributes that have changed over time
- Consideration of manufacturing processes & changes
- Details of sample preparation and extractions not sufficiently discussed
- Proactive gap assessment of revised standards

Other items

- Clear rationales for any tests not conducted/presented
- Chemical characterization testing (especially legacy devices)
 - Justification of test method(s) selected
- Organization: Tests not individually bookmarked and referenced
- No evidence that biological safety evaluation connects to risk management

GSPR 10.4.2 (CMR / ED Substances)

Please provide objective evidence supporting the statement that the device contains no CMR, endocrine disrupting substances, or phthalates?

How complete is the information on components and manufacturing aids that you obtained from your suppliers?

Common Questions

What, if any, additional testing or analysis was performed by you as the manufacturer?

Please clearly outline what CMR / ED substances have been identified in the device and at what concentration (w/w)?

Manufacturing & Process Validations

- It is required to include full manufacturing validations in MDR submissions (MDR Annex II, Section 3b)

(b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;

- Protocols and reports of critical process validations are required, not just summary
- Overall summary or Master Validation plan is still helpful to understand overall strategy and process
 - Include pointers to all detailed supporting documents
- Clear link between PFMEAs, manufacturing processes, incoming inspections and inline tests etc. for completeness and control.
- Process validations: what was run, including justifications for tests conducted, sampling rationale, raw data, product range covered.

Ensure English versions are provided

Inspection Information – why is BSI asking for this?

- Incoming, in-process and final inspection checks and the results (Annex VII 4.5.3)
- Common question – *"Why is this being requested outside the QMS audit?"*
- MDR requires that the NB review this as part of the Annex IX technical documentation assessment (not only QMS audits)

4.5.3. Product verification

Assessment of the technical documentation

For assessment of the technical documentation conducted in accordance with Chapter II of Annex IX, notified bodies shall have sufficient expertise, facilities and documented procedures for:

- the allocation of appropriately qualified and authorised personnel for the examination of individual aspects such as use of the device, biocompatibility, clinical evaluation, risk management, and sterilisation, and
- the assessment of conformity of the design with this Regulation, and for taking account of Sections 4.5.4. to 4.5.6. That assessment shall include examination of the implementation by manufacturers of incoming, in-process and final checks and the results thereof. If further tests or other evidence is required for the assessment of conformity with the requirements of this Regulation, the notified body in question shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Lifetime in Use

- Lifetime of the device should be defined by the manufacturer (GSPR 6)
 - How is evidence of performance over lifetime demonstrated in testing and clinical use?
 - Post-Market Surveillance & PMCF plans should be suited to gathering data through the device lifetime (Art. 83, Annex XIV)
- Special device types:
 - Implants
 - Article 18 (Implant card and information to be supplied to patient): Expected lifetime of the device and any necessary follow-up
 - SSCP: Information about the expected lifetime of the device including data on implant survival rates
 - Software
 - Lifetime of the device may be determined by hardware, or other required software

Clinical Evaluation – Some Common Gaps

Equivalence not demonstrated

Incomplete Safety & Performance data with respect to all indications/claims

Clinical benefits and risks not clearly addressed

Clinical benefits not measurable

Safety and performance endpoints not clearly defined

Patient population not clearly defined

State of the art not clearly established

Missing or incomplete clinical development plans

Competence of the CER authors/reviewers

& many more....

Article 18 (Implant Card and Info to be Supplied)

What Article 18 documentation should manufacturers submit?

1. Explanation/justification for the solutions adopted by the manufacturer to meet art. 18 requirements and MDCG guidance.
2. Implant card drawing (back and front) and sticker drawings (if applicable)
3. Implant card specification
 - Physical/mechanical and material/chemical specifications for card (and stickers if applicable)
4. Informative instructions leaflet (or justification for not providing)
5. Art. 18.1 (b-d) information
 - Patient information leaflet
 - screen shots from patient information website, hyperlink to working website etc.
6. Usability validation protocols/reports

Improving Technical Documentation Submissions



TD Submissions - Remember to Include:

- ✓ Information to allow the design stages applied to the device to be understood (Annex II Section 3a)
- ✓ Design Specifications or Design Inputs, etc. (Needed for Annex II Section 3)
- ✓ All Process Validations and associated Validation Plan (Annex II Section 3b)
- ✓ Risk Management Plan (Annex I, GSPR 3a)
- ✓ Clinical Evaluation Plan as well as Clinical Evaluation Report (Annex II Section 6.1c)
- ✓ Device-specific PMS Plan (Annex III), and PMCF Plan (if applicable) including proactive elements (Annex XIV)
- ✓ Incoming, in-process and final inspection checks and the results (Annex VII 4.5.3)

New requirements compared to MDD/AIMDD or often missed

TD Submissions - Additional Topics To Consider:

- ✓ Manufacturer personnel support
- ✓ Document availability
- ✓ Languages
- ✓ Certificate scope
- ✓ Subcontractors and Suppliers
- ✓ Accessories
- ✓ Novelty



Improving TD submissions – Final Thoughts:

- ✓ Regulations and regulators are clear that MDR is a new stand-alone application
- ✓ Make the documentation a numbered, fully searchable, bookmarked PDF and easy for the reviewer to navigate. Know your audience – provide context and evidence – tell the story.
- ✓ Read the salient portions of the MDR and the associated MDCG guidance documents and address these to the best of your ability/understanding
- ✓ **A complete and well-organised technical documentation file decreases the time and cost of the review.**



BSI Medical Devices – Use Our Resources

<https://www.bsigroup.com/en-GB/medical-devices/resources>

Brochures, Guides and Documents



MDR guidance

- [MDD Best Practice Guidelines >](#)
- [MDR Best Practice Guidelines >](#)
- [MDR Mapping Guide >](#)
- [MedDev 2.7.1 Rev 4 changes >](#)
- [MDR Conformity Routes >](#)
- [MDR Readiness Review >](#)

Webinars

MDR Conformity Assessment Routes webinar



MDR - What we know



Download the presentation >

White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators will no longer require manufacturers to have a regulatory expert - a Person Responsible for Regulatory Compliance (PRRC) - at their disposal. To ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the indicators of these differences? What controls are necessary to ensure AI in healthcare is safe and effective?

Medical device clinical investigations – What's new under the MDR?

The content of a clinical investigation is one of the most time-consuming and resource-intensive activities for a medical device manufacturer to face. The paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

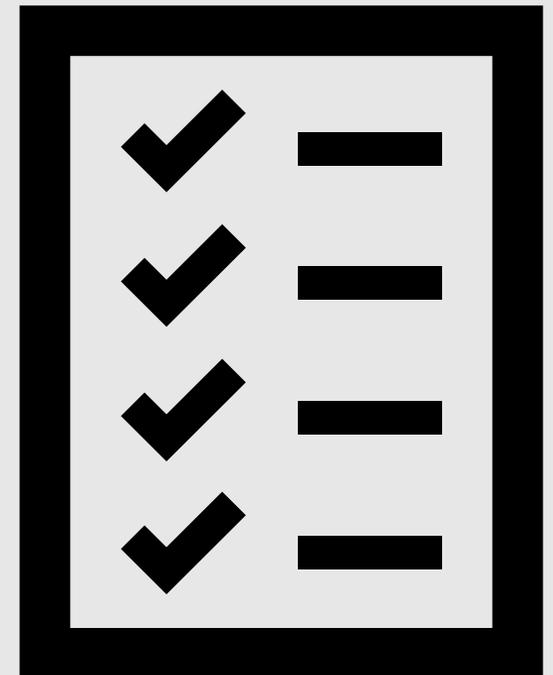
Training Resources



Medical devices regulation (MDR)	
Transition from MDD to MDR	1 day
Technical Documentation for CE - Marking	1 day
Requirements of MDR for CE - Marking	1 day
Implementing of MDR for CE- Marking	3 days
Further courses for medical devices manufacturers	
Medical Device Single Audit Program (MDSAP)	2 days
ISO 14971 Risk Management	1 day
Creating and Maintaining Technical Files	1 day
Post-market Surveillance and Vigilance	1 day
Clinical Evaluation for Medical Devices	1 day
Process Validation for the Medical Device Industry	1 day
Introduction to Medical Device Software	1 day

Recap

1. MDR Technical Documentation Review Process
2. Common Gaps or Questions from MDR Technical Reviews
3. Improving Technical Documentation Submissions
4. Questions





Questions?

Available medical devices training courses include:

CE marking training courses

- MDD to MDR Transition
- Requirements of the MDR for CE Marking
- Implementation of the MDR for CE Marking
- Introduction to Medical Device Software

Specialist training courses

- Post Market Surveillance and Vigilance under MDR and IVDR
- Technical documentation for the MDR
- Remote Auditing

Visit our website at
bsigroup.com/training
to find out more and
book your place

Thank you for joining today

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