Medical Devices Regulation

AIMDD to MDR transition - what you need to know

Concetta Gallo, Jazzmyne Buckels, Thomas Doerge
Active Implantable Medical Devices, BSI

23 November 2021

By Royal Charter

Your Speakers Today

Concetta Gallo

Technical Team Manager,
Active Implantable Medical Devices
BSI

Thomas Doerge

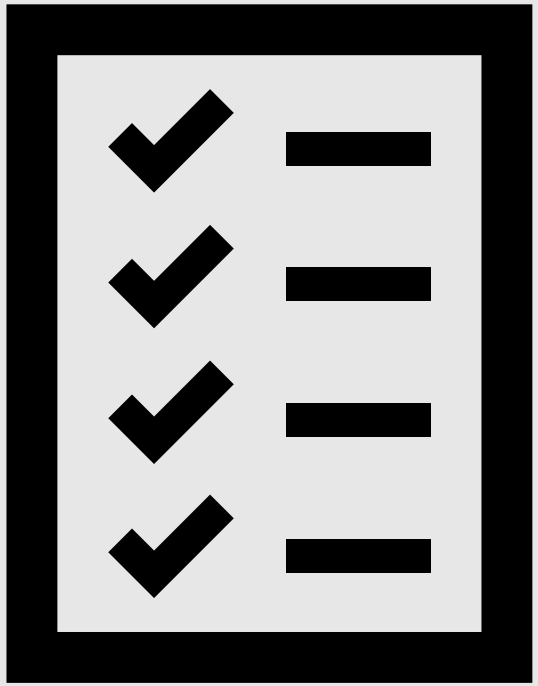
Global Head,
Active Implantable Medical Devices
BSI

Jazzmyne Buckels

Technical Team Manager,
Active Implantable Medical Devices
BSI

Agenda

1. BSI Introduction
2. Pre-submission Guidance
3. MDR Application Processing
4. Post Approval Requirements
5. Questions



Why BSI?

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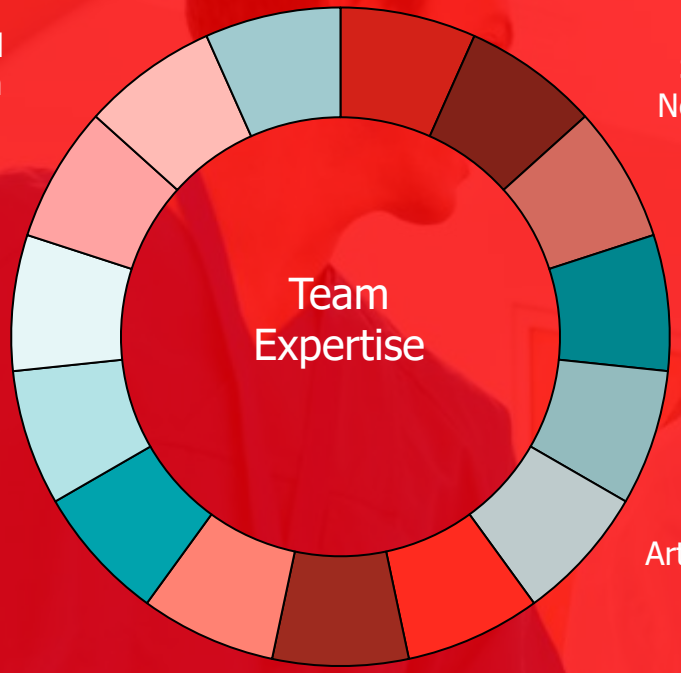
AIMD Team Expertise



Peripheral Nerve Stimulation
Deep Brain Stimulation
Phrenic Nerve Stimulation
Hypoglossal Nerve Stimulation
Sacral Nerve Stimulation
Muscle Stimulation
Vagal Nerve Stimulation
Spinal Cord Stimulation
Subcutaneous Neuromodulation
Epilepsy Monitoring
Brachytherapy
Blood Vessel Volume Sensors
Musculoskeletal Bone Growth Systems
LVAD's
Artificial Heart
Breast Tissues Expansion Systems
Hydrocephalus Shunts
Therapeutic Ultrasound Systems
Implantable Infusion Pumps
PA Pressure Sensors
Pacemakers
Implantable Cardiac Defibrillators
Ascites Pump
Implantable Glucose Sensors

AIMD Team Combined Experience

455 YEARS

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Pre-Submission Preparation & Considerations

How to best prepare for MDR Application

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Pre-Application process

Benefits to Clients include:

- Applications all stored in one place digitally
- View up to date status and actions required
- Single adaptable application form for all RS schemes
- Validation
- Complete history of the application

BSI provides full quotes for the MDR certification process including all rounds of questions!

Clients should talk to their commercial contact, and they will arrange access. For new clients without a BSI personal contact, they can complete a short online form (www.bsigroup.com/en-GB/medical-devices/forms/contact-us-med-dev/) to establish contact with the Commercial team, who will then arrange access to the portal after initial discussions with the potential client.

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

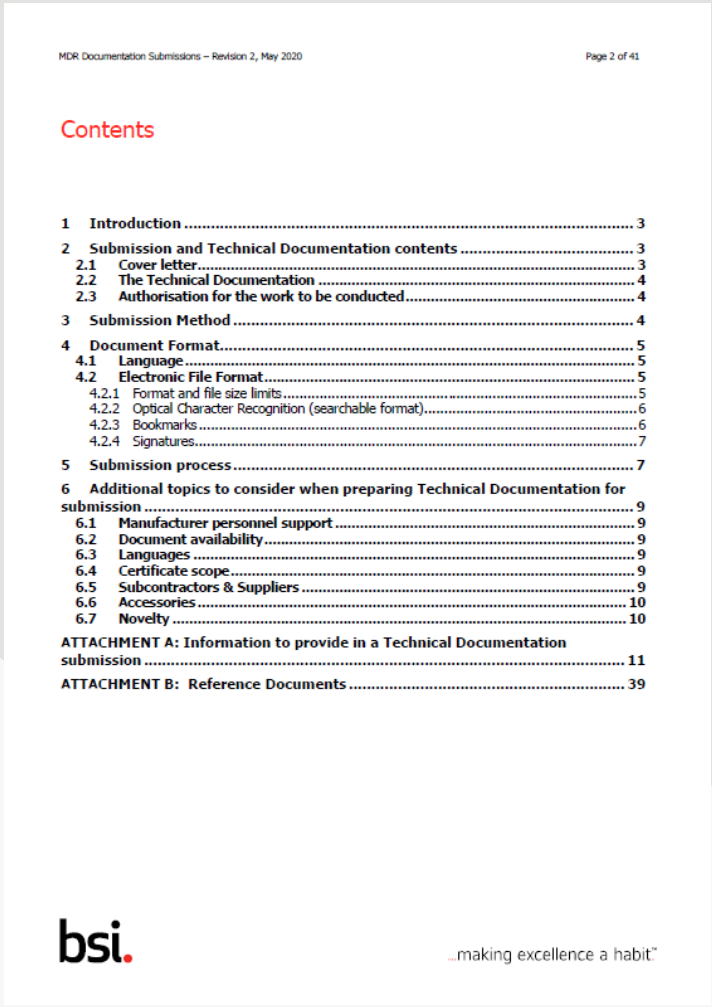
- **Incomplete Submissions** - all the information needed for the review not provided
- **Poor structuring of Technical Documentation** – information present but difficult to locate.

Improving TD submissions

- ✓ 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.**

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.



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

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Classification of AIMDs and their accessories

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Which of the following devices would be considered as classIII under the MDR?

a) Implantable nerve stimulator

b) Torque wrench

c) Implantable leads for pacemakers

d) Magnet for Implantable Pulse Generator

e) All of the above

MDR Annex VIII and MDCG 2021-24 Guidance on classification of medical devices

October 2021

Rule 8 - Im

- are act ed as class I

Accessori
implanta

Rule 9 - A ll as active dev

- all acti g the perfor

For exam vices for AIMDs

- **Article 58 :** It is necessary, in particular for the **purpose of the conformity assessment procedures**, to **maintain the division of devices** into four product classes in line with international practice. **The classification rules**, which are based on the vulnerability of the human body, **should take into account the potential risks** associated with the technical design and manufacture **of the devices**. **To maintain the same level of safety** as provided by **Directive 90/385/EEC**, **active implantable devices should be in the highest risk class**.
- **As well non-active/non-implantable accessories** to an AIMD **support the intended use** of the **active implantable medical device** and therefore cannot be down-classified on their own right.
- **The intended use of the system needs to be considered** and therefore all accessories are **class III**.

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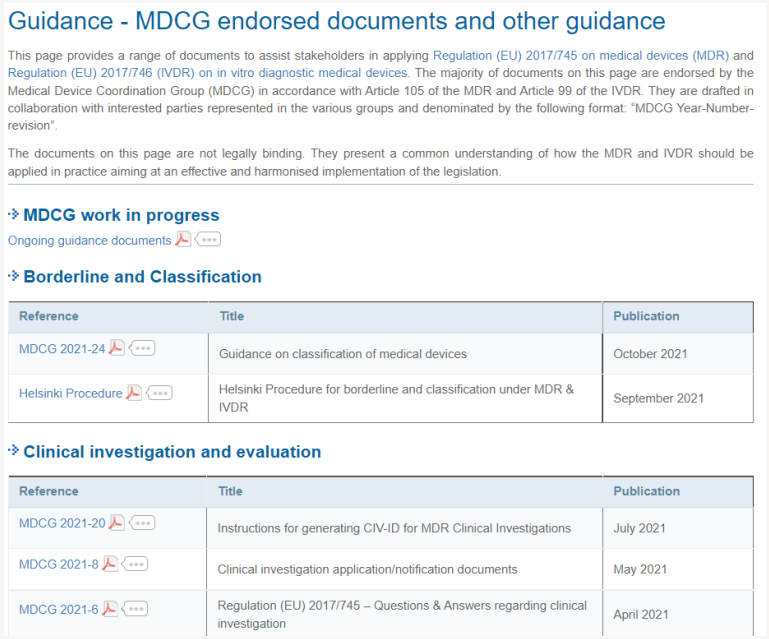
It is important to follow the EU Guidance Documents because…

— 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 - Annex VII Section 4.5.1



Guidance - MDCG endorsed documents and other guidance

This page provides a range of documents to assist stakeholders in applying Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices. The majority of documents on this page are endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR and Article 99 of the IVDR. They are drafted in collaboration with interested parties represented in the various groups and denominated by the following format: "MDCG Year-Number-revision".

The documents on this page are not legally binding. They present a common understanding of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation.

MDCG work in progress

Ongoing guidance documents

Borderline and Classification

Reference	Title	Publication
MDCG 2021-24	Guidance on classification of medical devices	October 2021
Helsinki Procedure	Helsinki Procedure for borderline and classification under MDR & IVDR	September 2021

Clinical investigation and evaluation

Reference	Title	Publication
MDCG 2021-20	Instructions for generating CIV-ID for MDR Clinical Investigations	July 2021
MDCG 2021-8	Clinical investigation application/notification documents	May 2021
MDCG 2021-6	Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation	April 2021

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

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

Harmonised standards – State of the Art

- Only 5 are harmonized to 2017/745 (MDR)
- MDCG 2021-5, Guidance on standardisation for medical devices, April 2021: *The most recent versions of standards with the technical solutions they contain reflect the "state of the art". The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution.*
- Present proactively a clear gap analysis if older version of standards used and most updated tests are provided in the latest standard.
  - For tests, address whether current standards are considered met, conclusion why additional testing was not required

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.

MDR Technical Documentation Review Process

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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-gb/documents/bsi-md-mdr-best-practice-documentation-submissions-en-gb.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	

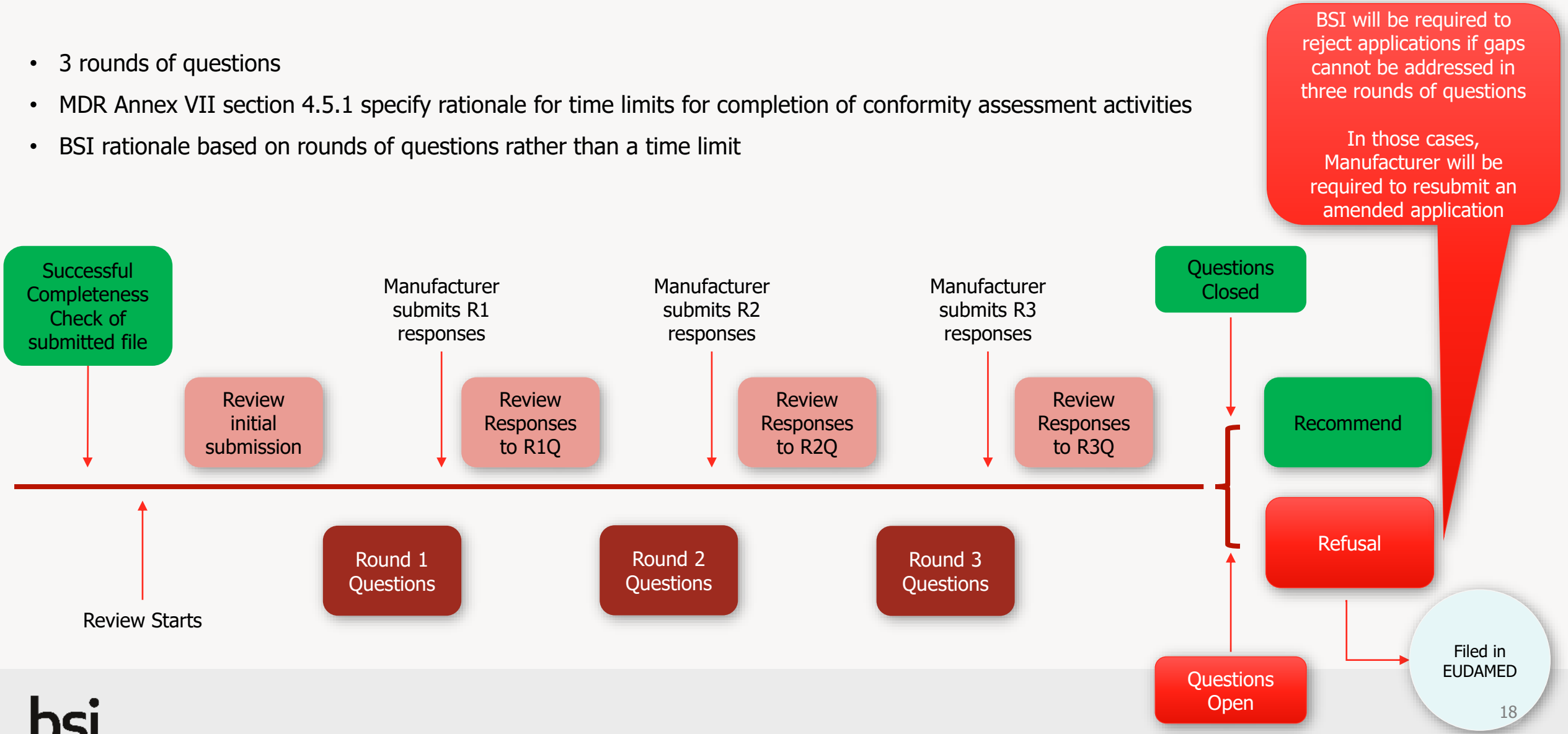
4.2 Technical Documentation Checklist

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		☐YES ☐NO
	MDF4900 – BSI Change Notification Form		☐YES ☐NO ☐N/A with justification
	Document index		☐YES ☐NO
	Top level (or summary) Technical Documentation (STED) file		☐YES ☐NO ☐N/A with justification
BSI Comments - Overview			
1. Device Description and Specifications Including Variants and Accessories			

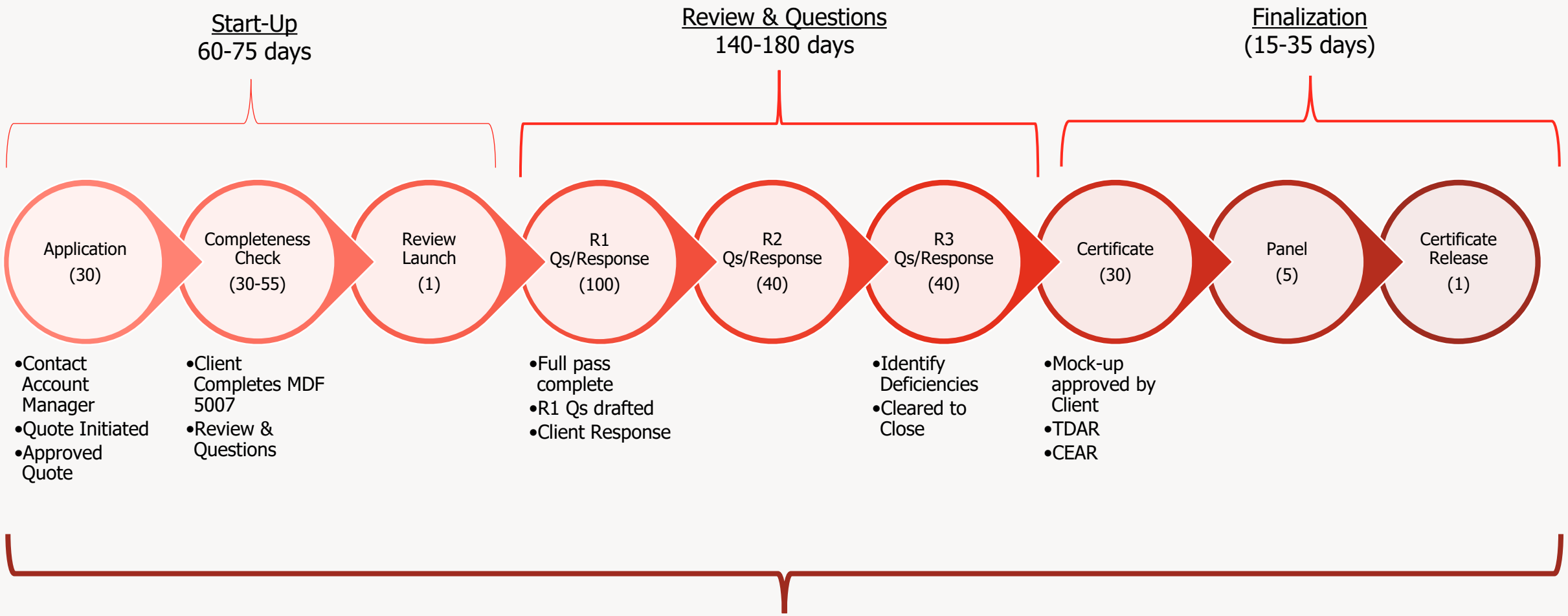
Section Title	Item	Location of the requested information; Mark as "N/A" if not applicable and provide a brief justification	BSI Completeness Check (To be completed by BSI)
1.1 Device Description	1.1.1 General description including product or trade names, principles of operation, mode of action etc		☐YES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

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



Review Timing



Overall Timeline
215-300 Days

External Impact to Review Timeline

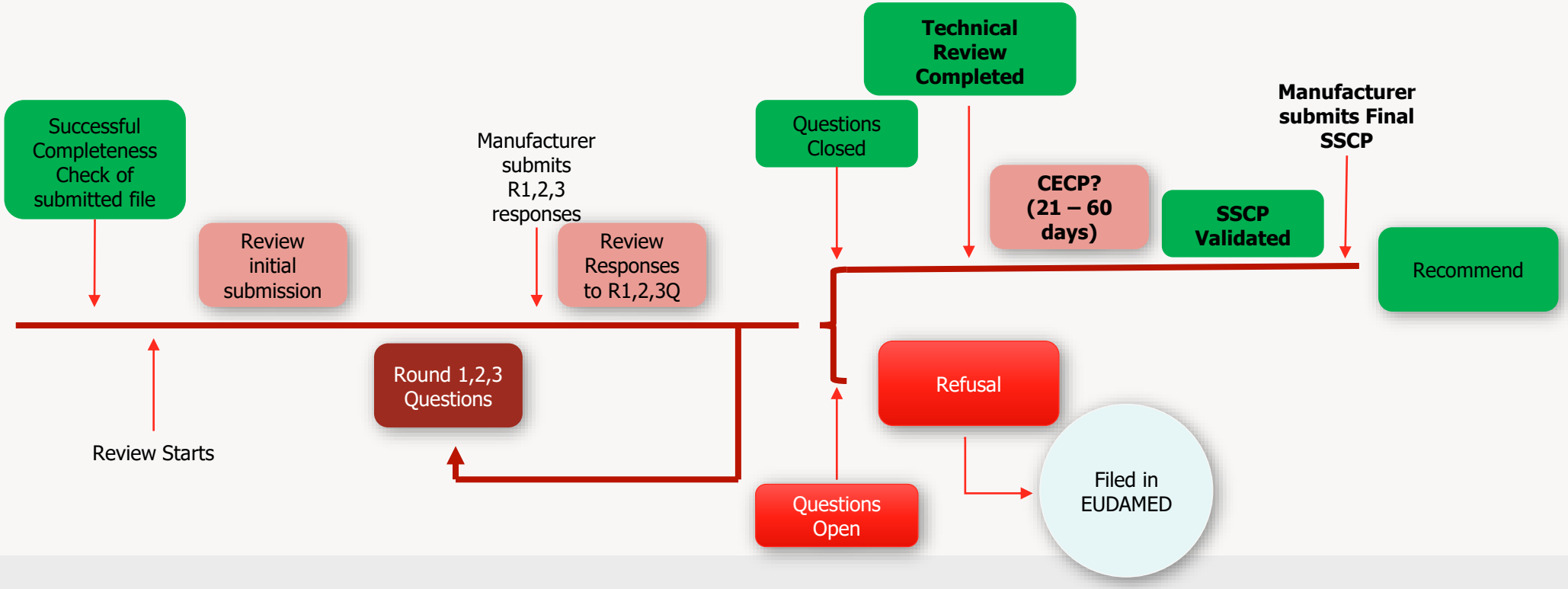
Medicinal Consultation (MDCG 2020-12)

- NBs are not designated to assess against 2001/83/EC and cannot make a decision on the quality and safety of the ancillary medicinal substance
- Competent Authorities & EMA have responsibility for the approval and control of medicines
- The medicinal products authority consulted shall provide its opinion to the notified body within 210 days of receipt of all the necessary documentation.

Delays to timeline defined in MDR be considered: COVID activities taking priority of the CAs, Limited number of CAs willing to conduct such assessments

External Impact to Review Timeline

- **Clinical evaluation consultation procedure CECP (MDCG 2019-3)**
- Already marketed devices under Directive transferred to MDR do not need CECP
- Every modification to design of the device that is affecting clinical data needs the CECP



Typical gaps in the technical documentation

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What area part of the technical documentation leads to the highest number of questions raised from reviewers?

a) Clinical

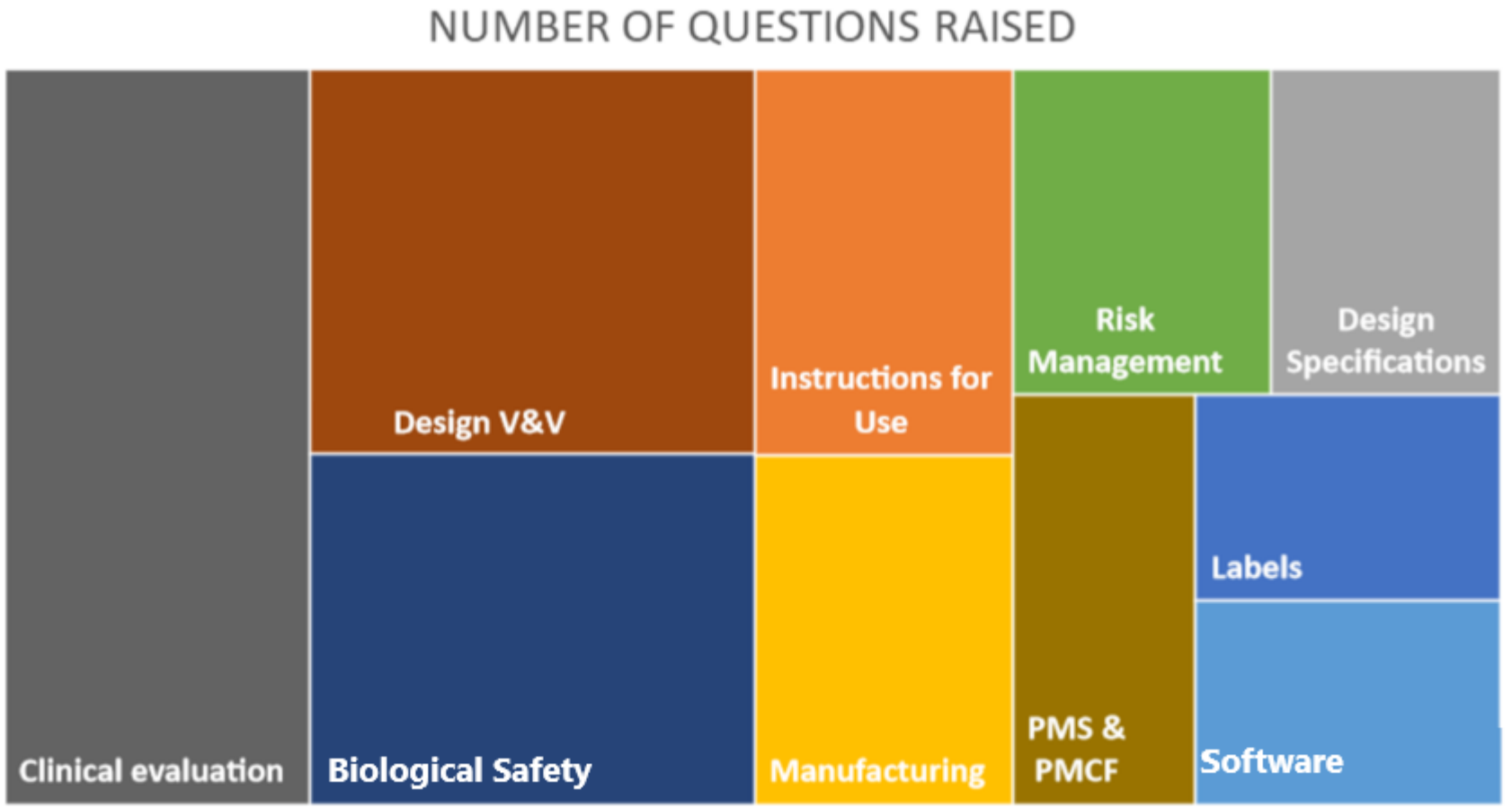
b) Biological Safety

c) Risk Management

d) Design V&V

e) IFU & Labels

Technical Documentation – Questions Raised



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

Tell the Story

Devices with a long history under the directive 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

Traceability – **a clearly traceable matrix** from requirements to reports and finally to raw data of performed testing is helpful to allow the review to be performed in an efficient way and is beneficial as well in respect of the review timeline.

Refer to BSI Best Practice Guidelines for additional guidance

What are the key clinical documents that are required in the initial submission under the MDR?

a) CER

b) CEP, CER, PSUR

c) CEP, CER, SSCP,
Clinical Study Documentation, PMS/PMCF Plan

Poll Answer

What are the key clinical documents that are required in the **initial** submission under the MDR?

C) CEP, CER, SSCP, Clinical Study Documentation, PMS/PMCF Plan.

- **All clinical data** will be evaluated for compliance to MDR. Original sources are expected.
- Clinical Study Compliance to ISO 14155 / MDR Annex XV is expected
- PMS/PMCF Plans Must follow MDR Annex III and MDR Annex XV Part

- **CER** must follow the **CEP**.
- **SSCP** must reflect **CER**.
- **PSUR** is not reqd. in initial submission *

* (PSUR reqd. under AIMD after August 2022, MDCG 2021-25)

Key Clinical Documents

Document	Key Contents	Key Considerations
Clinical Evaluation Plan (CEP)	**Outlines:** Relevant GSPRs, Intended Purpose, Intended Clinical Benefit, Intended Safety, Evaluation Methods, Evaluation Measures/Parameters, Consideration of Specific Components, Clinical Development Plan (CDP)	Article 2(53) – "Clinical Benefit" MDR Annex XIV 1(a) – "Clinical Evaluation Plan"
Clinical Evaluation Report (CER), Clinical Study Protocols + Reports	**Evaluates:** State of the Art, Equivalence, Literature, Investigations, Appraisal of data quality / quantity, Analysis against GSPRs and SotA, Conclusions and Gaps to be addressed by PMCF.	MDR Article 61 MDR Annex XIV Part A, XV. MDCG 2020-5 MDCG 2020-6
Summary of Safety and Clinical Performance (SSCP)	**Summarizes:** Intended Purpose, Device Description, Clinical Alternatives, Standards, Clinical Evidence, Users and Training, Residual Risks (etc.).	MDR Article 32 MDCG 2019-9 "SSCP"
PMS Plan	**Collection and analysis of field data**, Identification and reporting of Vigilance & Trends, Identification and procedures for Corrective actions, etc.	MDR Article 84-88 MDR Annex III
PMCF Plan	**Generation of new Clinical Data,** to address where equivalence used, long term risks and benefits, identifying systemic misuse, etc.	MDR Annex XIV Part B, MDCG 2020-7, MDCG 2020-8

Clinical Review – Common Gaps

Intended Purpose & Patient population insufficiently defined	Clinical benefits & claims not defined & measurable	Performance & safety parameters not clearly defined & justified	State of the art not fully established
Equivalence Incomplete	Literature Review Protocols not defined, justified or validated	Clinical Data is not appraised for sufficient Quality and Quantity	Clinical Evidence is not fully evaluated against clinical benefit claims, GSPRs, and state of the art
Gaps in clinical data not identified / PMCF plan does not address gaps	Risk Analysis does not align with Clinical Evaluation	IFU / SSCP does not fully align with CER / Risk Analysis	PMS Plan does not address all requirements in Articles 84-88 and Annex III

Key Technical Documentation

Documents	Key Contents
General device info	Description Classification Market history Intended Purpose
IFUs & Labelling	Physician/Patient Manual eIFU Product/Packaging Labels
Design & Manufacturing Docs	Design Specs Manufacturing Specs Legal Manufacturer Subcontractors
GSPRs	Trace Matrix GSPR Checklist Standards Applied
Risk Management	FMECAs, FMEAs, Hazard Analysis, Risk Management File Risk Procedures PMS Data
Verification & Validation	Biological Safety/Sterilization Verification/Validation Protocols & Reports Usability Data Software Protocols/Reports Stability/Shelf Life/Packaging

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 – i.e. Lead

Specification Origin of Spec.	Acceptance Criteria	Testing Protocol/Report	Sample Tested	Justification for Sample Tested	Location in TD
1.01 – Flex Fatigue EN 45502-2-1. (23.5)	>82000 cycles no fracture	P/R2013-06 – New SS Design t=0 P/R2013-08 – New SS Design t=X	Acme Lead 2.0	Same subject device under application	Appendix 83 t=0 Appendix 84 t=24
1.02 – Electrical check Manufacturer spec	30≤X<50 Ω	P/R2011-03 – Acme t=0 P/R2011-05 – Acme t=X	Acme Lead 1.0	Lead same as current 2.0 version under application; specification not impacted by suture sleeve change to 2.0	Appendix 86 t=0 Appendix 87 t=24
1.03 – Leakage Current EN 45502-2-1. (23.3)	Leakage current ≤ 2mA	P/R2011-03 – Acme t=0 P/R2011-05 – Acme t=X	Acme Lead 1.0	Lead same as current 2.0 version under application; specification not impacted by suture sleeve change to 2.0	Appendix 86 t=0 Appendix 87 t=X
5.11 – Pouch Seal Strength EN Iso 11607-1 and Manufacturer Spec.	> 1Lbs	P/R2009-02 – CathBot t=0 P/R2009-05 – CathBot t=X+	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=X+

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

Clearly present Annex I / GSPR Compliance

Possible Questions

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.

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

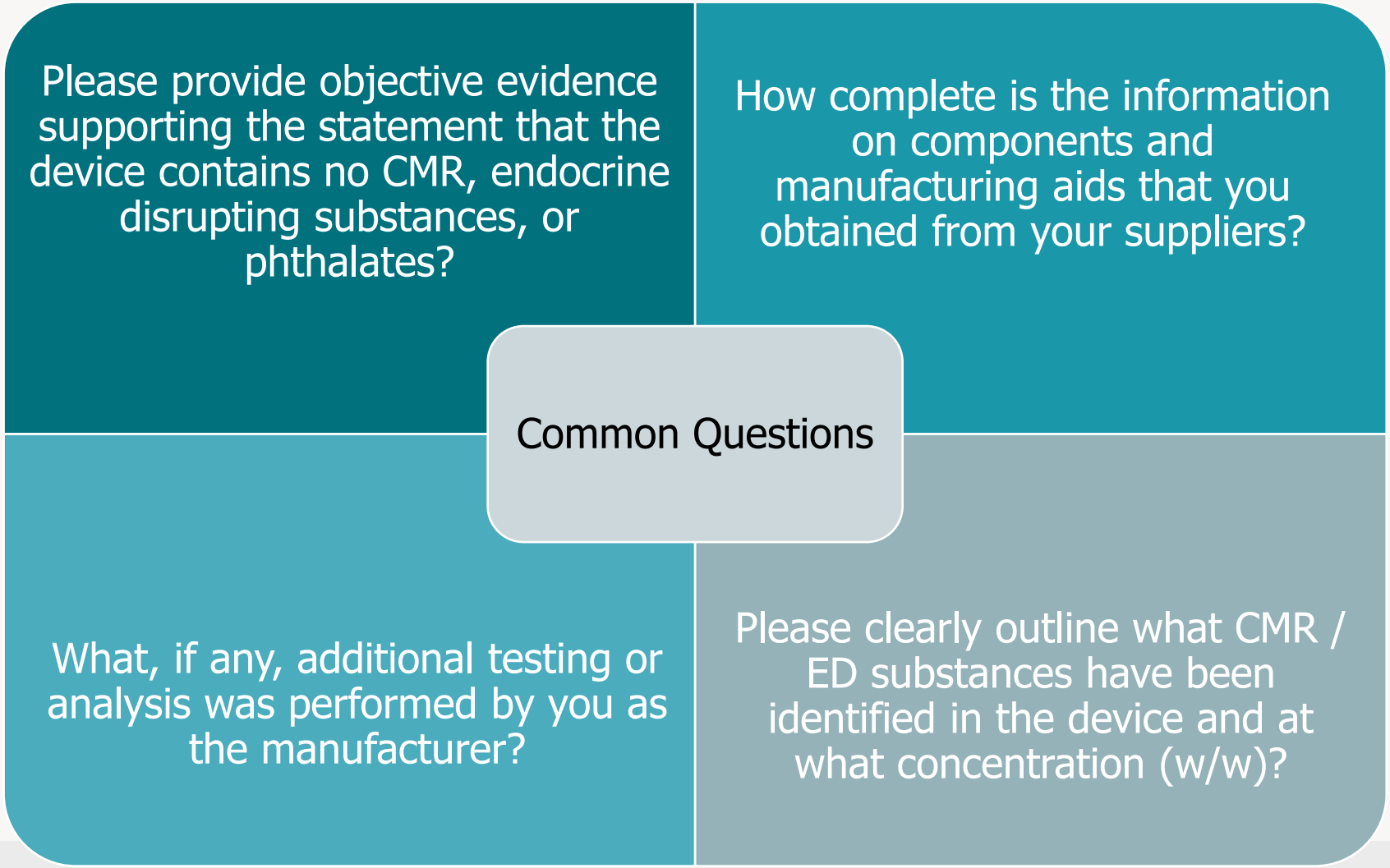
Context of tests not clear

- 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)



Manufacturing & Process Validations

3. DESIGN AND MANUFACTURING INFORMATION

(a) information to allow the design stages applied to the device to be understood;

(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;

(c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

MDR Annex II, Section 3b

- It is required to include full manufacturing validations in MDR submissions
- 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.

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)

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.

Software V & V – Some common gaps

EN 62304 checklist/trace matrix - Missing or not detailed enough - referenced documents not provided

For PEMS, EN 60601-1 Clause 14 – Additional requirements missing - (e.g. independent validation, allocation of risk controls to system architecture)

MDCG 2019-16 for cybersecurity not considered or applied - missing or insufficient cybersecurity risk assessment, security maintenance plan, security V&V testing

For SW executing on mobile platforms, clear requirements and associated testing not defined

For SW executing on mobile platforms, SOTA standard IEC 82304-1 not considered or applied

Where iterative/agile methods are used, version identifiers subjected to formal V&V testing not clearly identified – Clear equivalence rationales to final product/SW required in such cases

Automated Tests - Test script code and plain-English description not provided; Raw test script output files not provided

For EN 62304 Class B and Class C SW, the Software Integration Testing strategy is not clearly defined (e.g. separate testing, combined with SW system testing, etc.)

Missing or insufficient known anomalies report – should include identifier, description, severity, risk, and justification for each remaining SW anomaly

Software user interfaces not sufficiently tested for usability (formative and summative testing as per EN 62366-1); or clear UOUP rationale not provided

Software and firmware versions used in prior clinical studies not clearly identified in the CER –equivalency rationales to those prior versions not provided or insufficient

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

General feedback on technical documentation

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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 AIMDD" without providing these test protocols/reports
- ✓ Avoid chain referencing
- ✓ Review file fully before submitting
- ✓ 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)

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)

Additional topics to consider:

New requirements compared to AIMDD

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

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Post Application Activities & Responsibilities

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Post Certification – Client Obligations

Certification is dependent on the following:

- **PMS** – Activities performed as per the plan and the requirements, including active and systematic collection of data, vigilance and trend reporting, etc. *
- **PMCF** – must be performed as per the plan and protocols as presented in the submission. BSI must be informed of any issues or changes.
- **PSUR** – becomes due under MDR in 15 months after certificate issuance (12 months data + 90 days to submit to EUDAMED). Please refer to Article 86. *
- **CEP/CER** – Updated as appropriate, including to address device changes or new clinical data becomes available and/or changes to risk/benefit profile of device.
- **SSCP** – Updated and submitted with device changes and when new data becomes available and/or changes to risk/benefit profile of device.
- **Audit –** Outcomes (recertification, microbiology, UAV & Continuous Assessment)
- **Renewal Assessments –** Every 5 years
- **Reporting and Assessment of Changes** – Manufacturer are required to report all substantial changes to certified products and require amendment of the certificate as appropriate

* For More Information also consult BSI Webinar on PSUR and Vigilance under the MDR (29 Sept 2021)

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 aim to ensure companies 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 implications of those 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 conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This 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 manifacturers	
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

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Questions?