Best Practice Pathways to Market Access for Your Medical Device

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Disclaimer

What is presented today is based on our current knowledge and interpretation of the MDR and the latest available MDCG guidance.

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Poll Question #1

What stage of the regulatory journey are you at?

- Introducing BSI
- CE marking services for medical devices
- How to apply for our services
- What to expect
- Resources
- Electrical safety testing services

BSI at a glance

Full Scope NB under MDR & IVDR

A UK and EU Notified Body for CE marking under 15 European Directives/Regulations

A certification body for schemes including ISO 13485, ISO 14001 and ISO 27001, ISO 42001

Local market access schemes

A global training provider

An auditing organisation for MDSAP

The UK National Standards Body

Testing service EN/IEC60601

Cybersecurity Services

AI – Assessment

CE-Marking Services

MDR + IVDR

Definition of a medical device

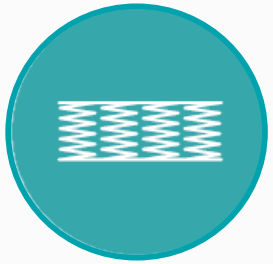
'Medical device' means any **instrument, apparatus, appliance, software, material or other article** … intended by the manufacturer to be used for **human beings** for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for injury or handicap,
- investigation, replacement or modification of anatomy or physiological process,
- control of conception,

… and which **does not achieve its principal intended action** … by pharmacological, immunological or metabolic means, but which **may be assisted** in its function by such means.

BSI Regulatory Services – Industries covered

Orthopaedic Devices
Joints, implants & cements



Vascular Devices
Heart valves, vascular grafts & stents

Active Devices
Medical imaging equipment, patient monitors & incubators
AI, SaMD

Microbiology and sterile devices
Devices, packaging & processes

In Vitro Diagnostic Devices
Pregnancy tests, blood glucose monitors & HIV tests

Dental Devices
Dental implants, coatings & instruments

Active Implantable Devices
Pacemakers, neurostimulators & radiation therapy devices

General Devices
Woundcare devices, ophthalmic devices, IVF devices & contraceptive devices

Devices utilizing animal tissue
Bone void fillers, dural grafts & haemostats

Device-Drug Combinations
Drug eluting stents, wound dressings & sutures

Poll Question #2

When should you initiate contact with a NB?

When do I reach out to the NB?

Initial contact

Preferably initial contact is established 12-18 months prior to technical documentation & QMS is ready for assessment.

Simultaneous start of EN/IEC 60601 electrical safety testing.

Quoting

Submission of Manufacturer (MFR) basic data 2-6 weeks

Current quoting time at BSI is 2-4 weeks

Decision time MFR?

Certification time

Best case scenarios

About 6 months Interactive Dedicated service*

About 12 months standard service*

Poll Question #3

What information should you have ready when contacting an NB for the first time?

Conformity Assessment Model Initial

1. Quality System

2. Microbiology

3. Technical Documentation

At BSI we conduct 3 separate assessments for QMS, microbiological and Technical Documentation review, and if appropriate product testing.

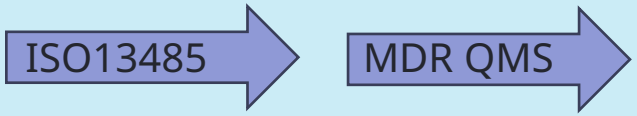
What is ISO13485

- The quality management system standard developed by the International Organization for Standardization
    - Certification is issued by a Certification Body
    - It indicates that the manufacturer has implemented and operates under an audited quality management **system** (not product-specific)
    - Gold standard to prove medical devices have been manufactured under a certified QMS

Two Optional Approaches

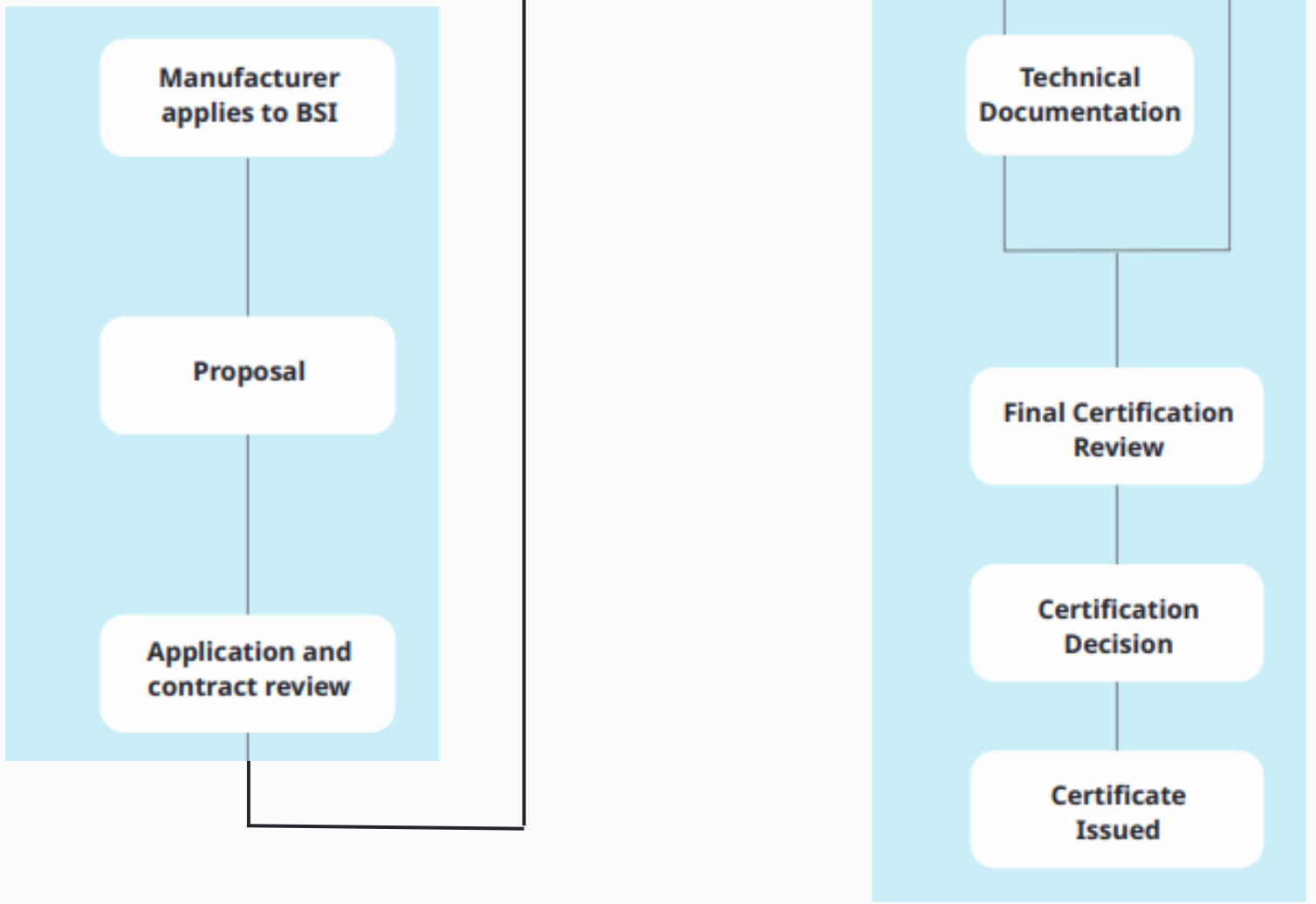
Sequenced Approach

- ISO 13485 certification first and MDR/IVDR later
- MDR/IVDR will still need a stage 2 audit but ISO 13485 certification can be achieved at an earlier stage (e.g. with limited scope for and Development activities only)
- One additional Stage 2 audit will be required for the MDR QMS



Parallel Approach

- Apply for both ISO 13485 and MDR/IVDR in one application
- One stage 1 audit and one stage 2 audit to cover all requirements of ISO 13485 and MDR/IVDR, full scope required



Post certification activities

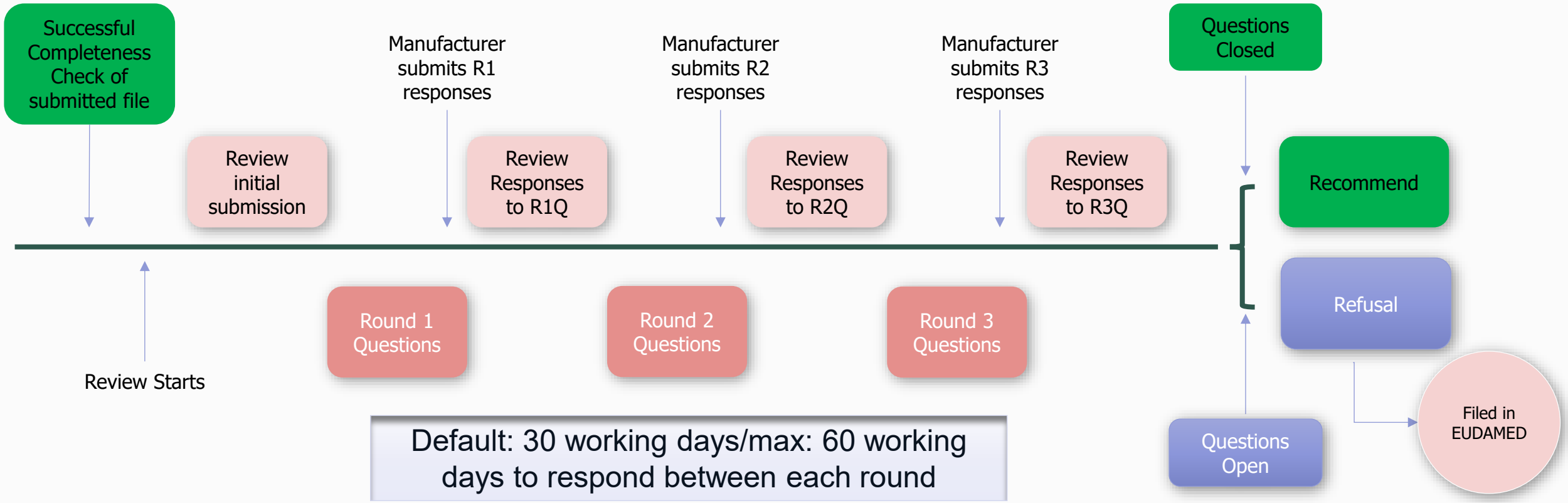
Once you are CE certified, BSI will continue to assess you through regular audits, including:

- QMS surveillance audits
- Technical audits for your CE certification
- Microbiology assessments, if applicable
- Unannounced audits
- Verification of manufactured batches (Class D IVDs)

Poll Question #4

How can you prevent delays in your journey to certification?

Technical Documentation Review Timeline



Value chain & Milestones for investment rounds

Contact with NB

Signed contract
ISO13485

Pass stage 2
audits

ISO13485 cert

Signed contract
MDR/IVDR

Pass stage 2
QMS audits

Technical doc
round 1, 2, 3

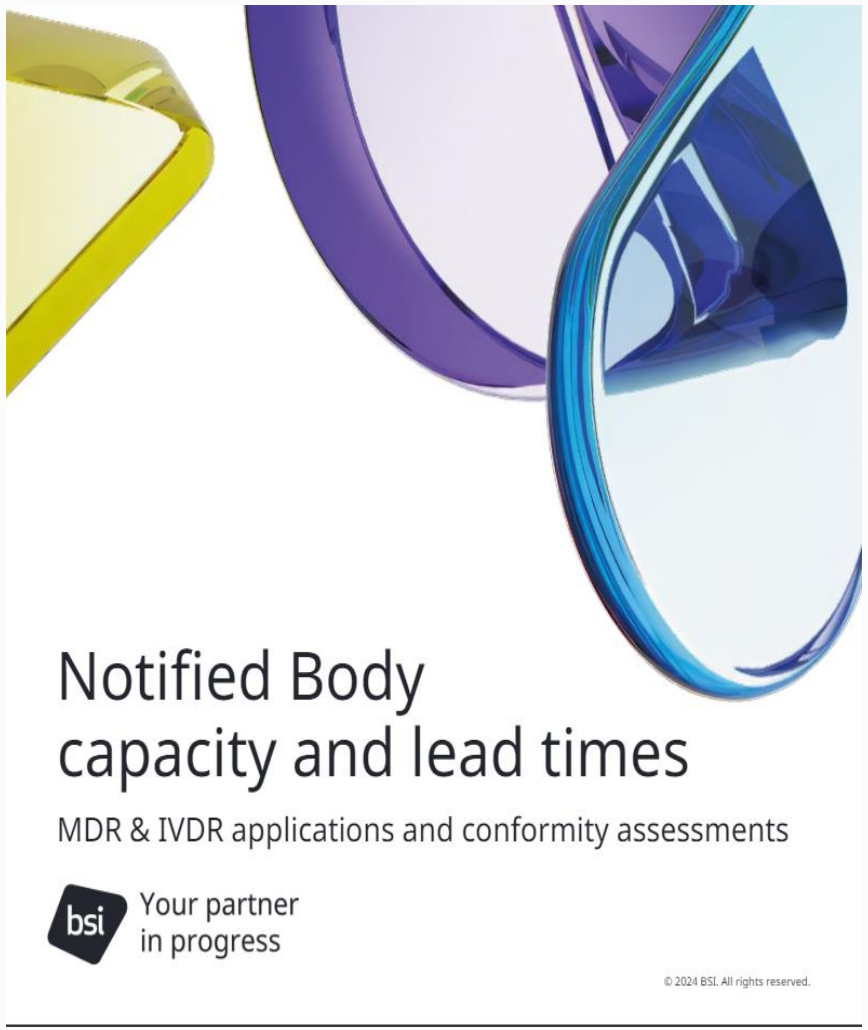
Panel review

MDR Certificate

Resources

Public website for NB capacity & lead times

https://www.bsigroup.com/siteassets/pdf/en/capabilities/medical-devices/bsi-md-nb-capacity-lead-times-en-gb.pdf



Technical Documentation assessments

Lead time for Technical Documentation assessments is measured as the average time BSI is able to start the review once complete technical documentation is submitted to BSI.

Last update: February 2026

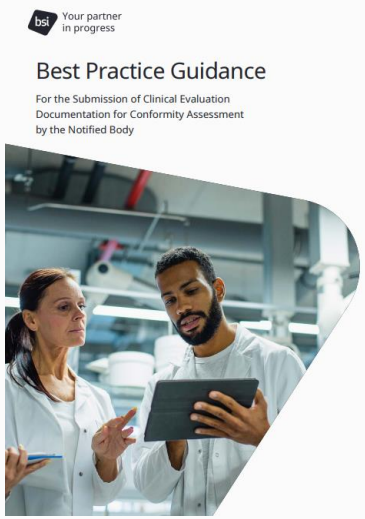
Technology Team	Type of devices	Device codes	Lead time	Change as of previous update
Active Devices	All active devices except stand-alone software medical devices (as shown below)	MDA 0201 – MDA 0204, MDA 0301 – MDA 0314, MDA 0316 – MDA 0318, MDS 1004, MDS 1009 – MDS 1012, MDS 1014	5 months	No change
Active Implantable Medical Devices	All types of AIMDs	MDA 0101 – MDA 0104, MDS 1009	4 months	No change
SaMD	Software as a Medical Device (SaMD) with or without Artificial Intelligence (AI)	MDA 0315	4 months	No change
General Devices	Contraceptives	MDN 1210	3 months	Plus 1 month
	Dialysis and other administration, channeling devices	MDN 1202	2 months	No change
	Soft tissue implants	MDN 1104, MDS 1012	3 months	No change
	Instruments	MDN 1208	3 months	No change
	Ophthalmic	MDN 1206	3 months	No change
	Wound care	MDN 1204	3 months	No change
	Anaesthesia, emergency, intensive care, and others	MDN 1201, MDN 1207, MDN 1211, MDN 1213, MDN 1214, MDS 1006, MDS 1010 – MDS 1012	3 months	No change

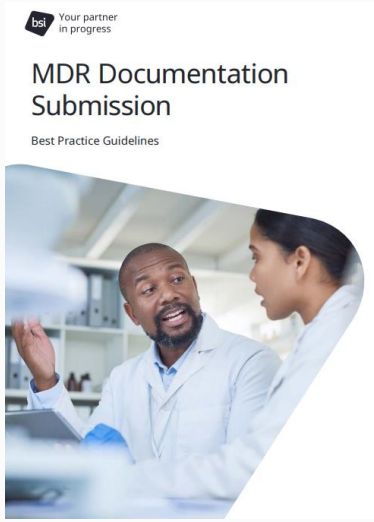
Structured Dialogue under MDR with BSI

Provide transparency and manage expectations:

1. Manufacturer sends questions to BSI
2. BSI engages the relevant competence based on the questions
3. Meeting is scheduled and the questions are addressed within the NB limitations of not providing consultancy

BSI guidance and whitepapers





Testing Services

Medical Devices standards

IEC/EN60601 General Safety & Performance

Meet regulatory and compliance requirements

- Electrical safety
- EMC
- IP

Market access

Certified Body - CB


X-Ray machines


OR equipment


Surgical robots


Software devices


Infusion pumps


Surgical drills

IECEE CB Scheme

- Use one test report to unlock electronic medical device market access in over 50 countries worldwide.

  United States (via OSHA-recognized NRTLs), Canada, European Union member states, United Kingdom, Japan, China, South Korea, India, Brazil, Mexico, Australia, South Africa, Singapore, Malaysia, and other Southeast Asian nations, as well as Gulf Cooperation Council (GCC) countries.

- Can be accessed via EN60601 test report

- Streamlines the path to market by reducing the need for re-testing or obtaining country-specific approvals for each region

Any questions?

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