

The First Step: Navigating Your IVDR Conformity Assessment

To prepare for a smooth delivery...

Alex Laan – Head of IVD Notified Body

Maria Kelly – Global Head IVD



Agenda

Welcome and Introduction

Understanding the role of the Notified Body under IVDR

How to navigate IVDR with confidence

Meet our IVD Experts

Preparing for your first conformity assessment

Fireside discussion and audience Q&A



Poll Question 1

//

Where are you in
your IVDR
certification
Journey?



Why BSI?



The power to deliver



Founded in
1901

70,000
clients

164,000
delegates trained
in 2024

6,674
colleagues

Clients in
195 countries

242,945
audit days in 2024

Creating impact through a unique combination of services and solutions



Regulatory Services



- Medical Devices (MDR/IVDR)
- Artificial Intelligence
- Product Certification



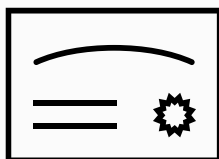
Notified Body – EU
Legislation, EU
Certificate



Approved Body – GB
Legislation, UKCA
Certificate



Certification Body –
ISO13485, ISO9001
Certificate



**Auditing
Organisation –**
MDSAP Certificate



The Changing Regulatory Landscape

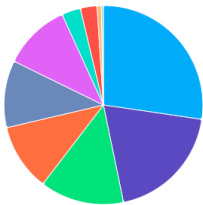
Proposal for a revision of MDR/IVDR

Proposal published in December 2025: [Medical devices and in vitro diagnostics – targeted revision of EU rules](#)

Feedback Period:
07 Jan 2026 - 03 Aug 2026

As of Sept 1st, 2026: 293 Valid Feedback Instances

By category of respondent



In preparation

Call for evidence

Commission adoption

Feedback: Closed

Feedback period
08 September 2025 - 06 October 2025

Feedback: Closed

Feedback period
07 January 2026 - 03 August 2026

Feedback: Closed

Commission adoption

Feedback: Closed

Feedback period
07 January 2026 - 03 August 2026 (midnight Brussels time)

[View feedback received >](#)

Proposal for a regulation - COM(2025)1023

English
(2.1 MB - PDF - 170 pages)

Download [↓](#)

Other languages (23) [↓](#)

Annex - COM(2025)1023

DISCLAIMER

This is a proposal only.
Many stakeholders to be involved and consultations.
Final text will probably look very different than what's being proposed.

Too early to speculate on what's likely to happen/not to happen – result probably in the middle between proposal and current legislation

EU MDR and IVDR legislative proposal; objectives

Simplification
and
proportionality

Reduction of
administrative
burden

Innovation and
availability of
devices for
special patient
groups and
situations

Predictability
and cost-
efficiency of
certification

Coordination
within a
decentralised
system

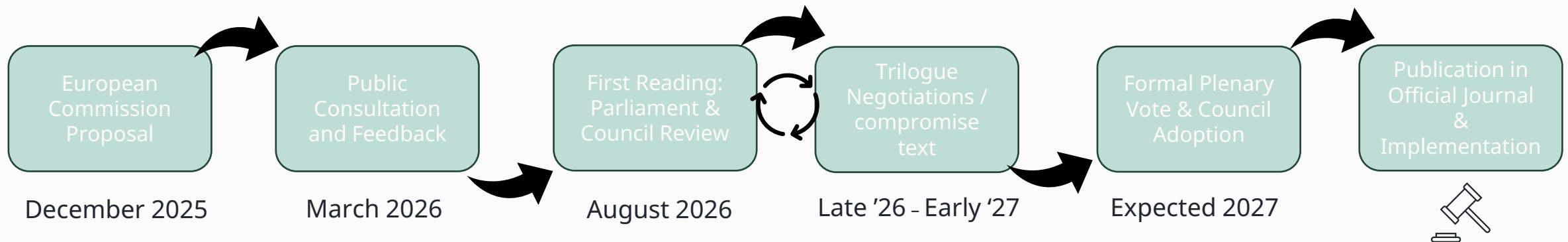
Further
digitalisation

International
cooperation

Interplay with
other Union
Legislations

Legislative process for changing (EU) MDR / IVDR

The assessment and adoption of the legislative proposal follow the ordinary legislative procedure / co-decision, involving both the European Parliament and the Council of the EU.



IVDR Transition Timeline (we are still in transit...)

	IVDR compliant QMS	Formal application lodged	Formal written agreement with a Notified Body signed	Transition deadline
IVDD certified devices ¹ ▶	26 May 2025	26 May 2025	26 September 2025	31 December 2027
Class D self-declared ² ▶				
Class C self-declared ² ▶		26 May 2026	26 September 2026	31 December 2028
Class B and A ² Sterile self-declared ▶		26 May 2027	26 September 2027	31 December 2029

Notes

¹ **IVDD certified devices:** IVDD Certification from a Notified Body.

² **IVDD self-declared devices:** IVDs on the market under IVDD that did not need a Notified Body Certification.

The sell-off period for self-certified IVDs already placed on the market under the IVDD has been removed. These devices can be made further available on the market without legal time restrictions. For in-house devices, the requirement to justify that an equivalent device is not available on the market is postponed until May 2028.

26 May 2022

- IVDR PMS and vigilance applies of all IVDs
- No new IVDD certificates issued by NB
- All new products to market under IVDR
- Class A devices must be IVDR compliant

Role as a Notified Body

Independent,
Designated under IVDR

Notified and monitored
by Competent Authorities

Not part of government,
private organization (not
consultants)



Full-scope Notified Body

- Capability to cover the breadth of all IVD Devices.
- All devices in your portfolio can be covered by one Notified Body
- Access to experience across multiple disciplines

**500+ Certificates
issued**



How To Navigate IVDR

Regulatory Challenges & Industry Impact

Few full scope designated NBs are available that can navigate the complex conformity assessment

Extensive GSPRs, clinical/performance evaluation requirements...

Proactive PMS required with PMPF studies that will require NB interaction...

Average IVDR approval: 12-18 months*

Clinical studies can be costly when not properly navigated...

Companies will need to prepare an effective vigilance system with EUDAMED coming online...

Continuous MDCG guidance updates that may have an impact on conformity...

Robust scientific validity, analytical and clinical performance data are required...

EUDAMED modules still being built → clarity required for manufacturers and Notified Bodies

*QMS and Product certificate

Our IVD Experts

Multidisciplinary expertise behind
every conformity assessment

The World's Leading IVD Notified Body Team of Experts

Our BSI team brings together senior scientific, clinical, regulatory, and industry specialists spanning leadership, technical assessment, clinical oversight, scheme management, certification, and operations. The team includes:



Global and Associate
Global Heads of IVD



Internal clinicians and
clinical oversight experts



Head of IVD
Notified Body



Scheme Managers and
Certification Specialists



Technical Team Managers
and QMS assessors



IVD Regulatory Leads (EU and UK)
and Operations support



Principle and Senior
Technical Specialists



215+

cumulative years of BSI /
Notified Body experience



650+

cumulative years of
industry experience

What This Means For You

The BSI teams' expertise, knowledge and experience supports you with **practical, proportionate, and trusted conformity assessment**, helping products reach and remain on the market with confidence under IVDR.

Our IVD team is globally distributed, supporting manufacturers like you worldwide with:

- Extensive scientific credibility
- Expertise to understand most IVD devices
- 650+ years cumulative experience behind your conformity assessment journey across IVD R&D, clinical laboratories, manufacturing, quality systems, and regulatory affairs
- Hands on industry experience that understands science and technology
- Global regulatory knowledge

In a Nutshell...

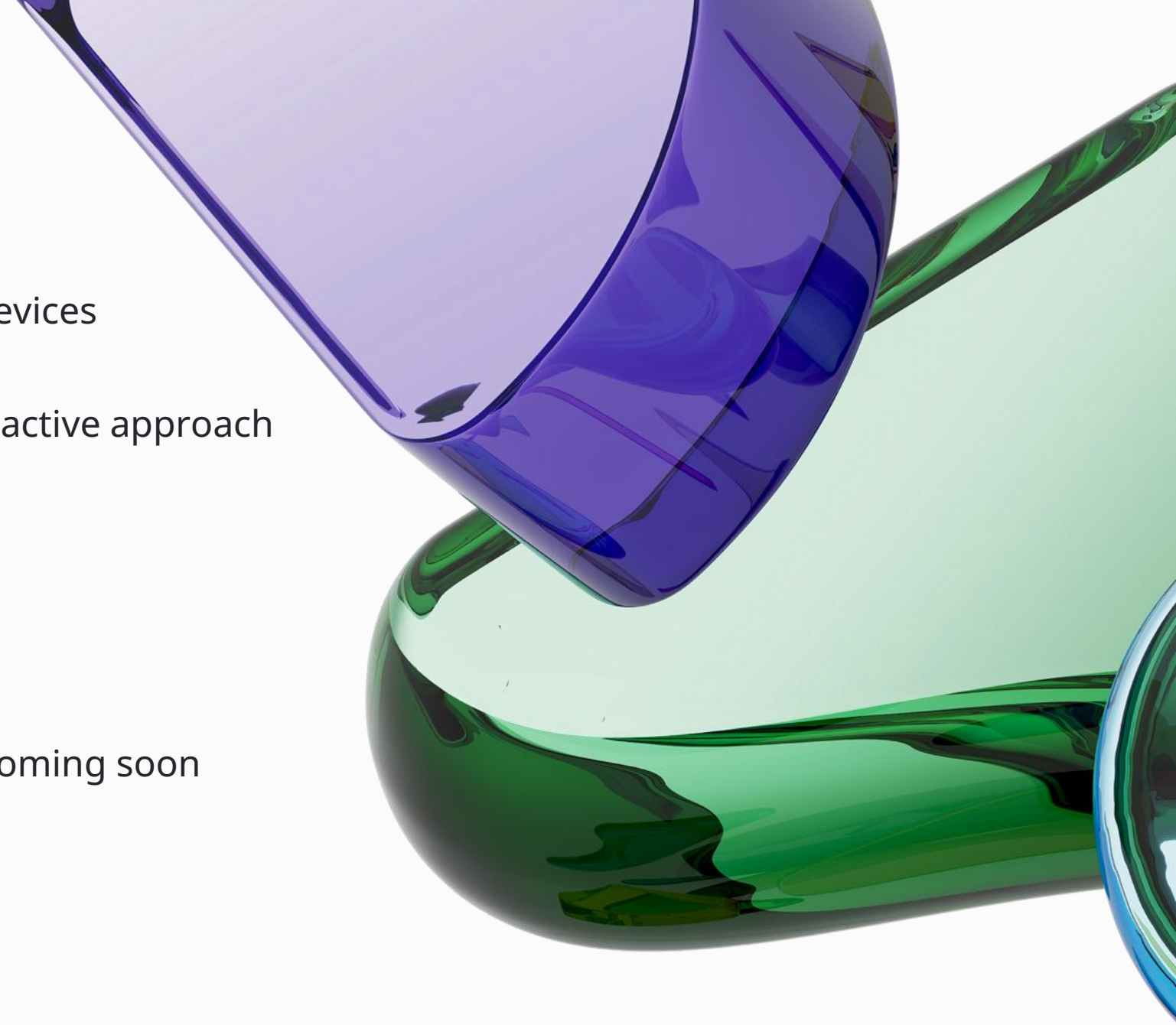
NBs are pivotal in access to safe devices

Regulatory changes require a pro-active approach

Plan ahead of what is coming

Make use of structured dialogue

Promising updates to legislation coming soon





Preparing for your first conformity assessment

Maria Kelly

Global Head IVD



Application Readiness

- Review IVDR requirements
- Assess relevant MDCG guidance
- Identify applicable international standards
- Review clinical / professional society guidelines
- Obtain manufacturer SRN
- Complete an application form



bsi **BSI Medical Device and IVD Company Information Form**

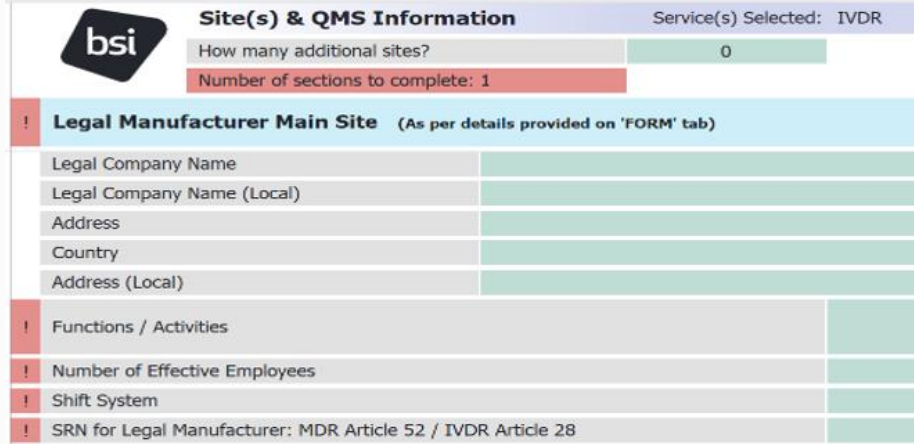
Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to support evaluations, and certifications. In order to start our quotation process we need certain information. For this purpose, we need your help in the lefthand column.

Please complete all fields marked with a red '!'

Select Service(s)

IMPORTANT - Please tick all you are applying for before moving to the next section

Article 16 - MDR	☐
Article 16 - IVDR	☐
Article 110 IVDR	☐
Article 117 MDR	☐
MDR	☐
IVDR	☐



bsi **Site(s) & QMS Information** Service(s) Selected: IVDR

How many additional sites? 0

Number of sections to complete: 1

! Legal Manufacturer Main Site (As per details provided on 'FORM' tab)

Legal Company Name	
Legal Company Name (Local)	
Address	
Country	
Address (Local)	
! Functions / Activities	
! Number of Effective Employees	
! Shift System	
! SRN for Legal Manufacturer: MDR Article 52 / IVDR Article 28	

Device Identification & Scope

- Define the device Intended Purpose - GSPR 20.4.1.c
- Determine IVDR classification – Annex VIII, MDCG 2020-16, MDCG 2019-11
- Confirm IVDR device codes – MDCG 2021-14
- Identify EMDN codes – EC EMDN website
- Assign a Basic UDI-DI (BUDI) for each device family – MDCG 2018-1

EU IVDR & UKCA Device Information			IVDR					
Number of sections to complete: 1								
IMPORTANT READ: Please input one device at a time and complete all fields marked with an '!' before moving on to the next device. If any questions contain multiple options please choose each answer row by row, and if adding a new device please enter the information against the next available device number.								
Device Number	Device Name List manufacturer product name (brand name). Product Group Name for Class Ir devices if being grouped using EMDN coding system.	Service Please specify the service for each device	Device Nomenclature Code	Basic UDI-DI	Part Number	Route to Conformity	Intended Use	IVDR Code
			GMDN for UKCA EMDN for MDR/IVDR Copy link below for extra code guidance for Article 16; https://webgate.ec.europa.eu/dyna2/en	Copy links below for UDI-DI guidance; https://health.ec.europa.eu https://ec.europa.eu/docs				Commission Implementing Reg (EU) 2017 / 2185 Copy link below for extra code guidance; https://eur-lex.europa.eu/eli/reg_impl/2017/2185/oj
Device 1	!							

Application Checklist

Signed contracts can only be accepted if the Application Checklist is completed.

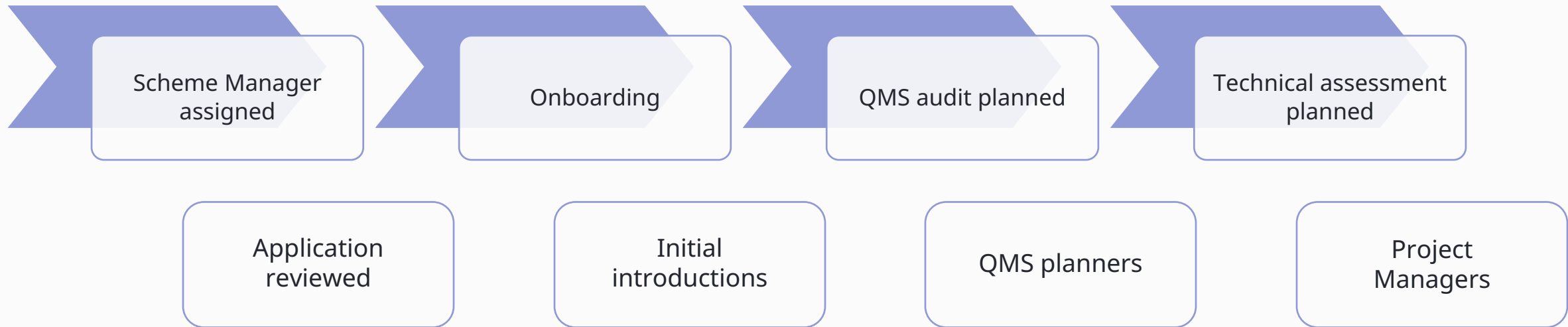
Documents in draft version are acceptable

MDR, IVDR CE application Checklist

Instructions for Manufacturers: Please complete the table below with the corresponding document references for the items specified and provide **English language** copies of the actual documents as attachments along with the signed BSI contract.

Document Type	Document References
Sample draft Declaration of Conformity (as per Annex IV of MDR/IVDR) for the highest classification device included in the application	
Quality Policy	
Quality Objectives	
Quality Manual	
PMS Procedure	
Sample PMS plan for the highest classification device (or groups of devices) included in the application	
Vigilance reporting procedures covering incident reporting, field actions, periodic summary reporting, and trend reporting	
A description of the procedures in place for keeping PMS plans, PMCF plans and vigilance procedures up to date	
Specific to IVDR Applications	
Sample performance evaluation plan for the highest classification device (or groups of devices) included in the application	
Procedures for keeping the performance evaluation plans up to date <u>taking into account the state of the art</u>	
Sample Post Market Performance Follow-up (PMPF) plan for the highest classification device (or groups of devices) included in the application	
Note: For self-testing, near-patient testing devices that are class B, class C or class D, if practicable and required, BSI may request an example of the device during the conformity assessment process.	

Next Steps



QMS Readiness

-
- Annex IX Chapter I – the manufacturer shall
 - EN ISO 13485 and EN ISO 14971
 - not compulsory but provide a well-established framework for demonstrating compliance
 - Annex VII section 2 – the notified body shall...

Poll Question 2

//

When is your
technical file due
to be ready?



Documentation Submission Readiness

- BSI IVDR submission best practices
- Complete the BSI Completeness Check document



Your partner
in progress

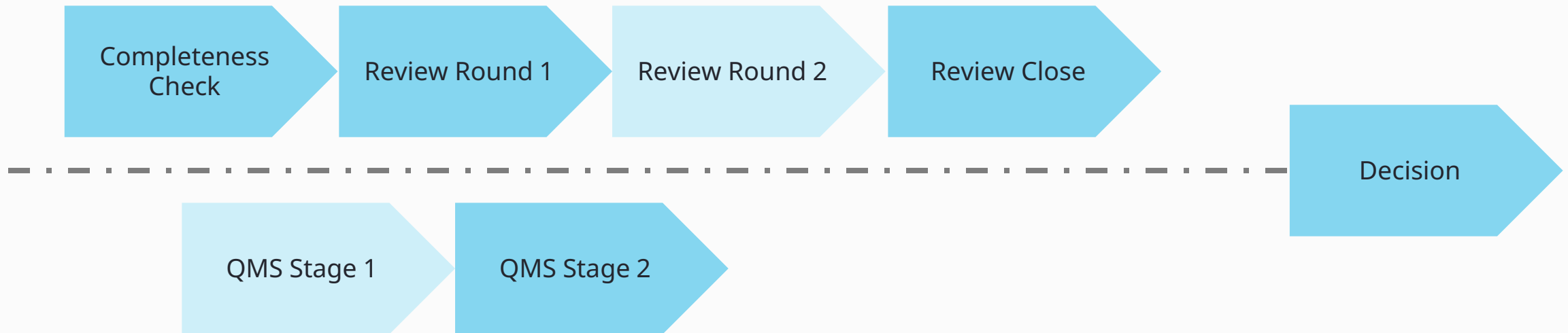
MDF9003

**IVDR Technical Documentation Completeness
Check**

Revision 3 (March 2025)

IVDR Review Process

The Review Process consists of a (or multiple) technical file assessment(s) and a Quality management system audit. Both can run in parallel.



Darker blue = mandatory, applicable to all. Lighter blue = if required

Life After Certification

Post **C**ertification

Your Partner in Progress...

Assessment

- Notified Bodies conduct assessments of devices to ensure they comply General Safety and Performance Requirements (Annex I) outlined in IVDR

Compliance Certificate

- NB issue EU (CE) Certificate once the device/QMS is found to be compliant with IVDR requirements which allows EU market access

Ongoing Surveillance

- NB perform periodic assessment of technical documents and QMS to ensure continuous compliance of certified devices/QMS

Fireside Discussion

Future IVDR Webinars

Global Webinars

Webinar 2 - Building The Foundation: Structuring Technical Documentation Is Key



22 October



09:00 BST or 16:00 BST

[Register Now](#)

Webinar 3 - Life After Certification: Thrive In The Era Of IVDR Compliance



10 November



09:00 GMT or 16:00 GMT

[Register Now](#)

125 bsi



In-person Events

EMEA Region:

Meet the Experts IVD - Amsterdam



24 November



09:00 - 16:30

[Register Now](#)

Exclusive Discount Code: **MTEIVDWEB30**





Engage Early...

Talk to us





Thank You

BSI Group

The Acre, 90 Long Acre, London

WC2E 9RA United Kingdom

bsigroup.com

