



CE-Certification of MDSW

Perspectives from the British Standards Institution

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Global Head AIMD and SaMD

10 March 2026



Disclaimer

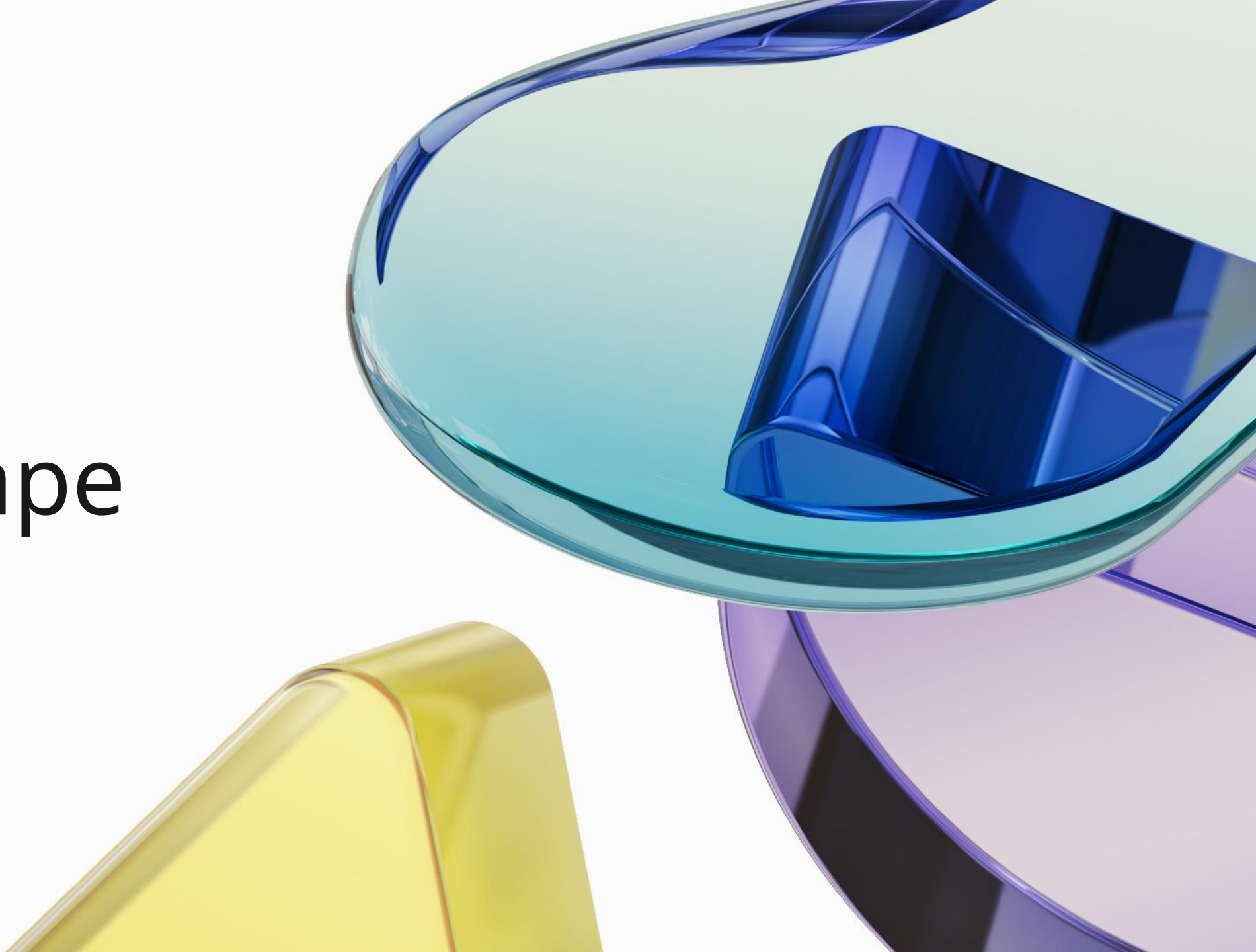
What is presented today is based on our current knowledge and interpretation of the MDR and the latest available MDCG guidance.

Agenda

- 1 Notified Body Landscape
- 2 Structured Dialogue
- 3 Certification Journey of MDSW
- 4 Typical gaps in submissions
- 5 Service levels
- 6 Timelines
- 7 Brochures, Whitepaper, Useful resources



Notified Body Landscape



What is CE Mark

A legal mark

CE mark is not a voluntary quality mark or owned by any Notified Body

CE marking indicates that the product meets certain statutory requirements connected with safety, health and environment.

Affixed by the Manufacturer

Certification issued by Notified Bodies (in most cases)

Manufacturers declaration of compliance with a specific legislation(s).

Notified Body (NB)



❖ Per Article 2(42) of MDR 'Notified Body' means a conformity assessment body **designated** in accordance with this Regulation

❖ Annex VII of the MDR contains specific detailed requirements for Notified Bodies covering organisation, quality system, resource and process requirements

❖ Notified Bodies get designated by Competent Authorities situated in each Member State

❖ The Notified Body is responsible for **conformity assessment** of manufacturers

❖ The Notified Body issues a certificate to demonstrate the manufacturer has met the requirements of the regulation

How to search for the Notified Body for your device?

Commission

Single Market Compliance Space

Home Notified Bodies Noise emissions Glossary

Home > Notified Bodies > Search by Legislation

Search by Legislation

Select Legislation name from the list below to find Bodies notified to carry out conformity

Legislation > (EU)2017/745

Search results (44)

Showing results 1 - 30

NOTIFICATION STATUS **Active**

LEGISLATION **Regulation (EU) 2017/745 on medical devices**

Search results (51)

Showing results 1 - 30

NOTIFICATION STATUS **Active**

LEGISLATION **Regulation (EU) 2017/745 on medical devices**

PRODUCTS **MDA 0315 Software**

Go to [NANDO website](#)

Search results (52)

Showing results 1 - 30

NOTIFICATION STATUS **Active**

LEGISLATION **Regulation (EU) 2017/745 on medical devices**

Body Number BSI > 2797

Search results (1)

NOTIFICATION STATUS **Active**

BODY NUMBER **2797**

Items per page: 30

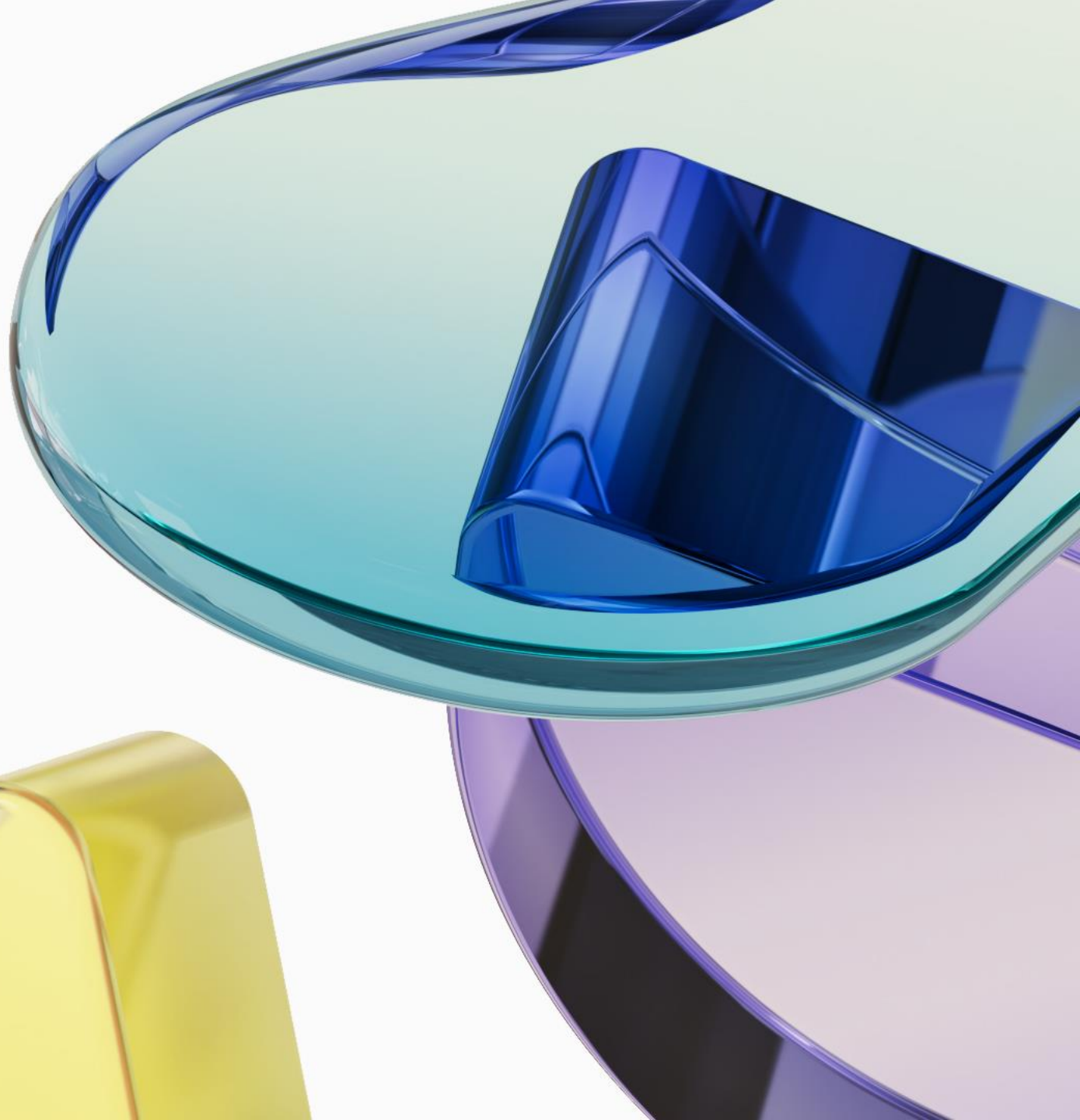
Body type	Body name	Country
NB 2797	BSI Group The Netherlands B.V.	Netherlands

MDA 0315 Software	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A)
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How can you
exchange with
your NB?





Your partner
in progress

Structured Dialogue with BSI



What is Structured Dialogue (SD)?



Per Annex VII (Section 1.2.3) Notified bodies are not permitted to provide services that may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they ***shall not offer or provide consultancy services*** to the manufacturer, or be ***linked to any organisation which itself provides consultancy services***.

MDCG 2022-14

MDCG Position Paper

Transition to the MDR and IVDR

Notified body capacity and availability of medical devices and IVDRs

August 2022

MDCG 2022-14:

*The MDCG encourages notified bodies and manufacturers to **organise structured dialogues before and during** the conformity assessment process aimed at regulatory procedures where this is useful **to enhance the efficiency and predictability of the conformity assessment process**, while respecting the independence and impartiality of the notified body. Such dialogues should not be considered consultancy service.*

MDCG 2019-6 (Revision 5)

MDCG 2019-6 is a document that helps notified bodies understand their obligations under Annex VII of the EU MDR and IVDR.

Medical Devices

Medical Device Coordination Group Document

MDCG 2019-6-Rev.3

MDCG 2019-6 Rev5

Questions and answers:

Requirements relating to notified bodies

Revision 5 - February 2025

- This document was updated to revision 5 in February 2025 and one of the areas that was updated was to provide clarity on structured dialogue.
- This update happened over 2 years since the publication of the MDCG 2022-14 which initiated the term '*structured dialogue*'.
- The guidance covers many important aspects around our independence and impartiality as a notified body. These should also be considered as part of structured dialogue.

What is and what is not considered consultancy?

MDCG 2019-6 information on what is considered and what is not considered consulting remain unchanged.

Consulting

- **Providing advice** to manufacturers, their authorised representatives, or suppliers **regarding solutions on how to fulfil regulatory requirements**.
- **Any involvement** in activities (e.g. **design, risk management, manufacturing processes**) related with the **devices or quality management systems** for manufacturers, their suppliers or subcontractors, except third-party conformity assessment activities.
- Other activities not specifically linked with the devices will be regarded as consultancy (e.g. **internal audits** to manufacturers or **client specific training**).

Not Consulting

- **General training** activities that are not client-specific - Trainings by the notified body, or a related body, are not considered client-specific if they are **open to the public, content and materials are not customized**, and attendance is not limited to one manufacturer or a manufacturer's suppliers/subcontractors.
- **Dissemination of informative material**, such as blog posts, guidance documents or informative presentations published by the notified body is allowed

MDCG 2019-6 Rev 5

Understanding Structured Dialogue

What falls under Structured Dialogue?

- Procedural aspects of pre-application and application processes.
- Notified Body assessment procedures, administrative details.
- High-level aspects of manufacturer's evidence of conformity or more complex combinations of clinical, technical, and regulatory conformity approaches.

What does not fall under Structured Dialogue

- Structured Dialogue is different from scientific advice which typically falls within the remit of the Expert Panels managed by the European Medical Agency (EMA).
- Structured Dialogue excludes the NB providing solutions to the manufacturer on how to comply with a specific legislative requirement(s).
- Structured Dialogue does not have any impact on future certification decisions for the device under application.

What can be asked during Structured Dialogue?

Open questions

Allow the Notified Body to provide feedback/questions to an approach.

Allowed

- "Can you help us understand BSI interpretation of Clause X?"
- "We are pursuing Article 61 (10), does BSI agree with this approach?"
- "We are struggling to find state of the art information on our device and have agreed these performance objectives, does BSI think these are suitable?"
- "Our PMCF plan focuses on X aspects, does BSI agree these are suitable activities?"

Closed questions

Any question focused on the Notified Body providing the solution to a problem will not be answered.

Not allowed

- "Can you tell us how we can...?"
- "Can you guarantee us that if we choose assessment route X?"
- "Can you tell us the Class of our device?"
- "What is the correct route to collect clinical evidence?"

Our structured dialogue

As a leading Notified Body, for over 20 years, BSI has been offering Structured Dialogues to enhance the efficiency and predictability of the conformity journey through all its phases, while respecting the independence and impartiality of the Notified Body.

Our approach to structured dialogue is highly collaborative. Various roles within BSI, including technical specialists, the commercial team, and scheme managers, engage at different stages of the process.

Pre-application

Examples of Dialogue topics

- Application process
- Conformity assessment process
- Lead times
- Project plan and client readiness
- Client information
- Indicative costs
- Organizational structure
- Transferring to BSI: the process

Application

Examples of Dialogue topics

- Commercial contract management
- Project management
- Client engagement
- Certification process
- Submission requirements
- Change management

Our Structured Dialogue is suitable for various types of organizations including: Startups, SMEs, large organizations, global enterprises

Post-Certification

Examples of Dialogue topics

- Ongoing technical and regulatory dialogue
- Ongoing Change Management Activities
- Project Management and general Client Support
- Compliance Management
- Recertification

Conformity assessment

Examples of Dialogue topics

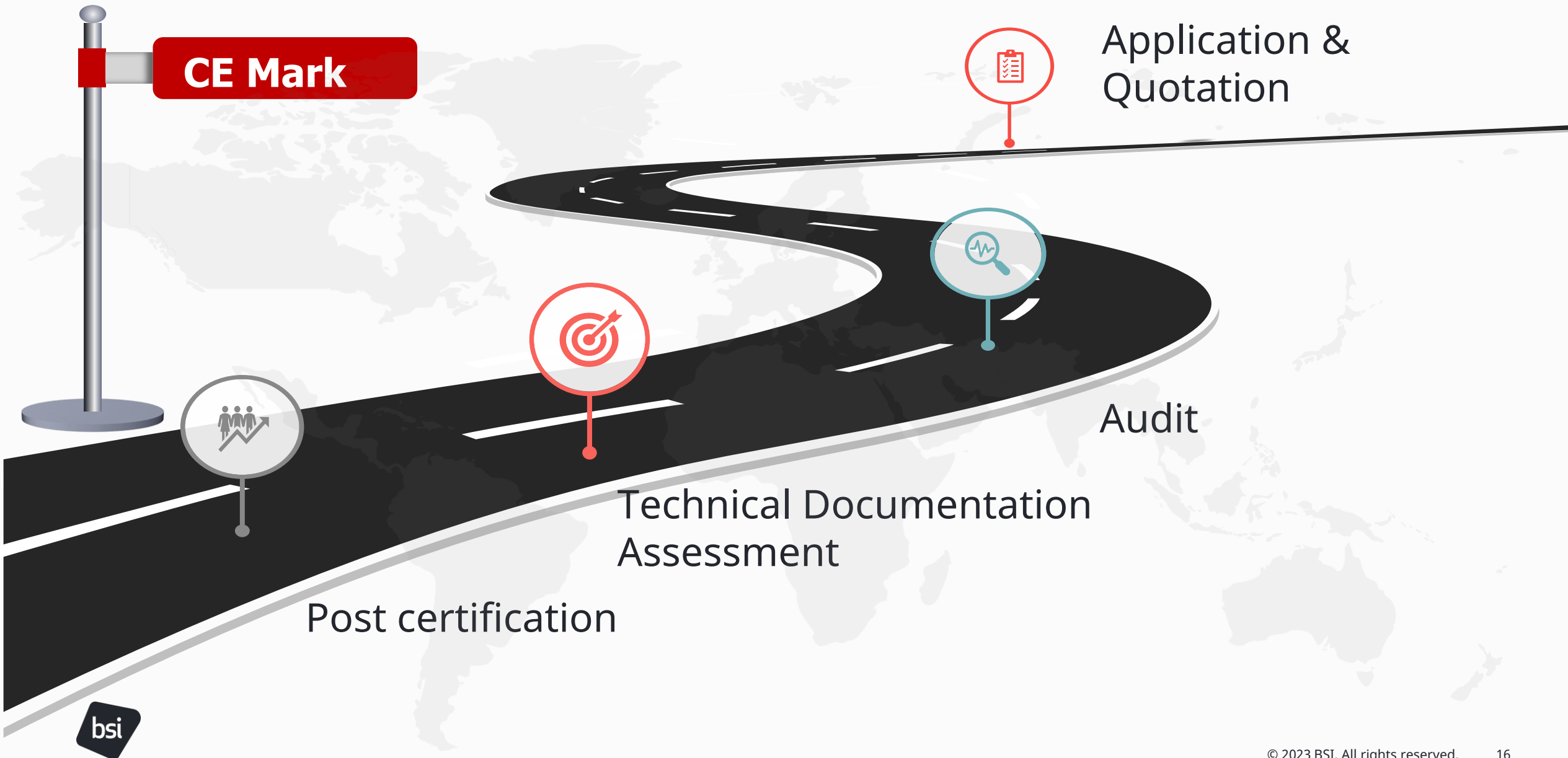
- Submission requirements
- Conformity assessment
 - Leveraging previous assessments
 - Conformity assessment activities and associated timelines
 - Clarification on assessment findings and missing data
- Completeness check
- Rounds of questions



Certification Journey of MDSW



Regulatory Services Client Journey



Regulatory Services Client Journey

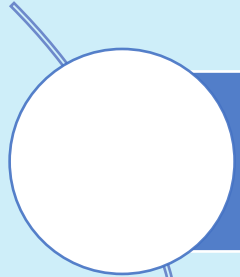
CE Mark



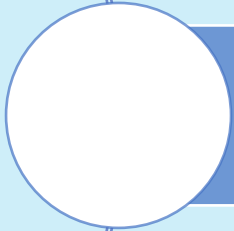
Application &
Quotation

Conformity Assessment

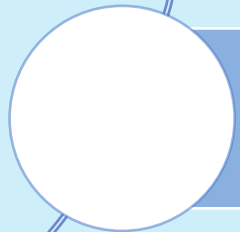
'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled – Article 2.40



Requirements, and conformity assessment routes – Articles 52, 54; Annex IX



Dependent on device classification



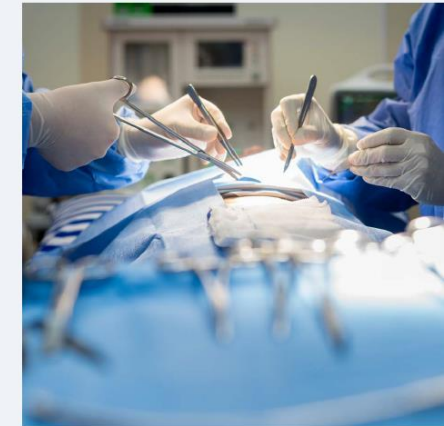
Conformity assessment Quality system based + Product assessment based (for high risk)

Conformity Assessment Routes

More than one route may be available for a given classification. The manufacturer chooses the route to conformity and the NB must verify the appropriateness and assess against the chosen annexes.

MDR	MDD	UKCA	Focus of Annex
Annex IX Chapters I and III Quality Management System	Annex II excl Section 4 Full Quality Assurance	Annexes same as Directives (except the legislation is different)	QMS based; Design, Manufacture, Final Inspection
Annex IX Chapter II Technical Documentation	Annex II Section 4 Design Examination	Annexes same as Directives	Product based; Documentation review
Annex X Type-Examination	Annex III Type Examination	Annexes same as Directives	Product based; Type testing + Doc review
Annex XI - Part B Product Verification	Annex IV Verification	Annexes same as Directives	Product based; Individual devices tested
Annex XI - Part A Production Quality Assurance	Annex V Production Quality Assurance	Annexes same as Directives	QMS based; Manufacture, Final Inspection
No equivalent	Annex VI Product Quality Assurance	Annexes same as Directives	QMS based; Final Inspection
Article 19 + Annex II, III	Annex VII Declaration of Conformity	Annexes same as Directives	For class I devices

● MDR Conformity Assessment Routes



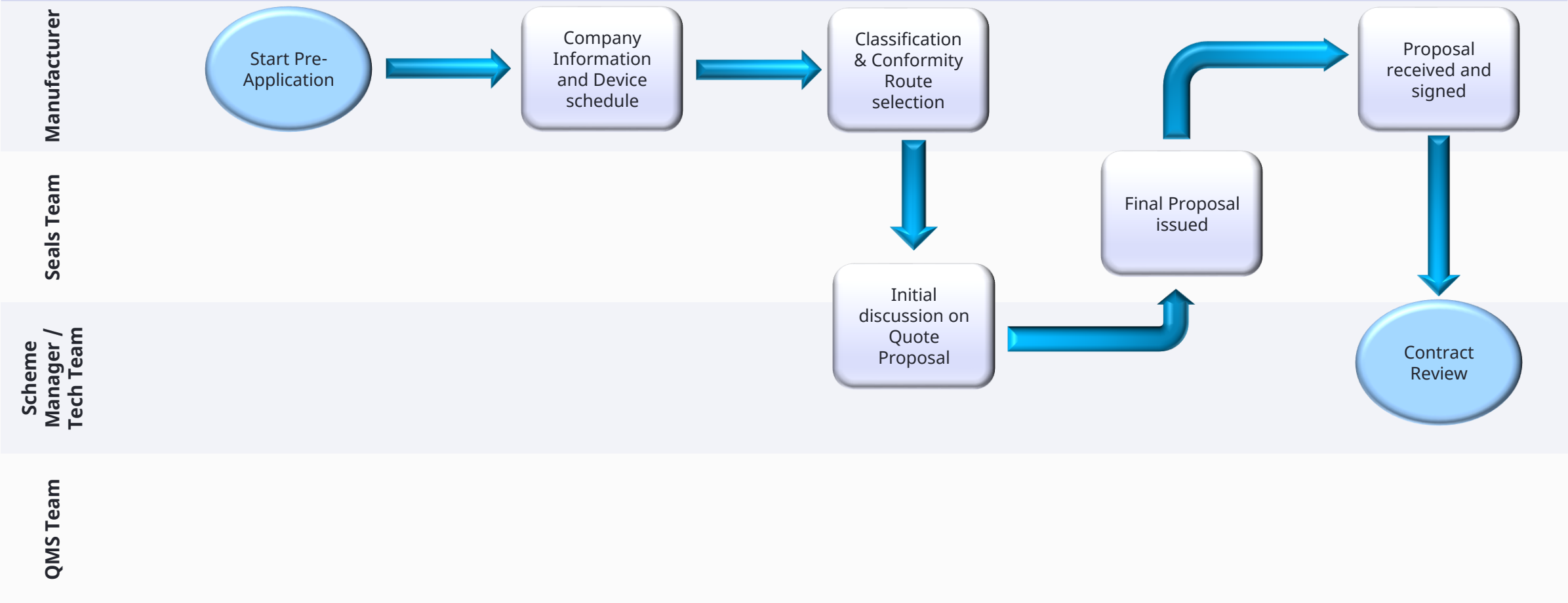
bsi.



<https://www.bsigroup.com/globalassets/meddev/localfiles/en-gb/documents/bsi-md-mdr-conformity-assessment-routes-booklet-uk-en.pdf>

Application Process with BSI

Application for certification



Regulatory Services Client Journey

CE Mark



Audit

Quality Management System Audit

Alongside the examination of the technical dossier the manufacturer is subject to an on-site audit of their quality management system ranging from witnessed testing at the production line, how they handle complaints and report vigilance issues to competent authorities. This is completed by a Notified Body QMS Auditor.



Regulatory Services Client Journey

A conceptual diagram showing a winding black road with white dashed lines, set against a light gray world map background. On the left, a silver stanchion holds a red rectangular sign with the text 'CE Mark'. In the middle of the road, a red circular icon with a target symbol is connected by a red line to the text 'Technical Documentation Assessment'. In the bottom left corner, there is a small black square with the white text 'bsi'.

CE Mark

Technical Documentation
Assessment

MDR Technical Documentation Completeness Check



MDF5007
Revision No 1 (December 2023)

MDR Technical Documentation Completeness Check

Inspiring trust for a more resilient world.

The contents of this document are confidential to BSI Group
The definitive version of this document is only available through the BSI BMS

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MDF5007
MDR Technical Documentation Completeness Check
Revision No 1 (December 2023)

Please note that any feedback provided by BSI in this checklist as part of the Completeness Check is based on a high-level check of the technical documentation submitted. It is possible that some of the information that could not be found is indeed available/present, but it just was not located or overlooked during the first pass check. If that is the case, please inform BSI where the information can be located. Also, please note that since this is a high-level completeness check, an affirmative indication below by BSI that all necessary information appears to have been adequately provided is not to be interpreted as a declaration or confirmation that the information provided has been assessed or evaluated for compliance to legislative requirements. Further, BSI may request additional documentation not already provided at any point of time during the formal technical documentation review if deemed to be required. Section 3 below provides additional guidance for the manufacturer.

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/en-GB/medical-devices/resources/>

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

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MDF5007
MDR Technical Documentation Completeness Check
Revision No 1 (December 2023)

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)
	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			
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
	For Artificial Intelligence (AI) devices or devices containing AI, information on AI models, techniques, architecture, and level of autonomy		
	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	1.4.1 List of type, sizes, configurations, variants etc. including catalogue numbers covered by the		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A with justification

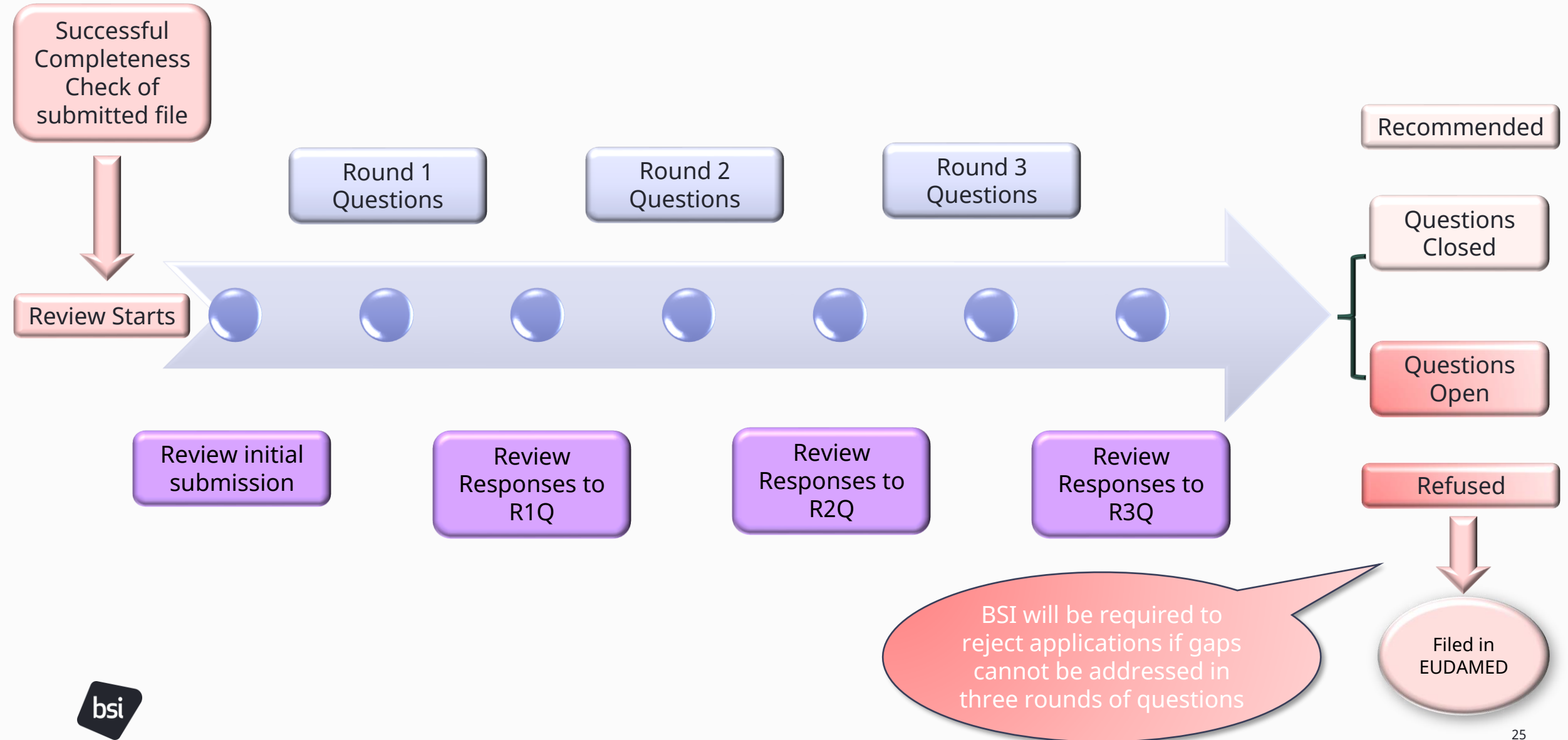
Inspiring trust for a more resilient world.

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Technical Documentation Review Flow in BSI



Regulatory Services Client Journey

CE Mark



Post certification

bsi

Post-certification – client obligations

PMS and PMCF

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.

CER/PSUR/SSCP

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.

Audits and certificate renewal

Audit – Outcomes (recertification, microbiology, UAV & Continuous Assessments...)

Renewal Assessments – Every 5 years

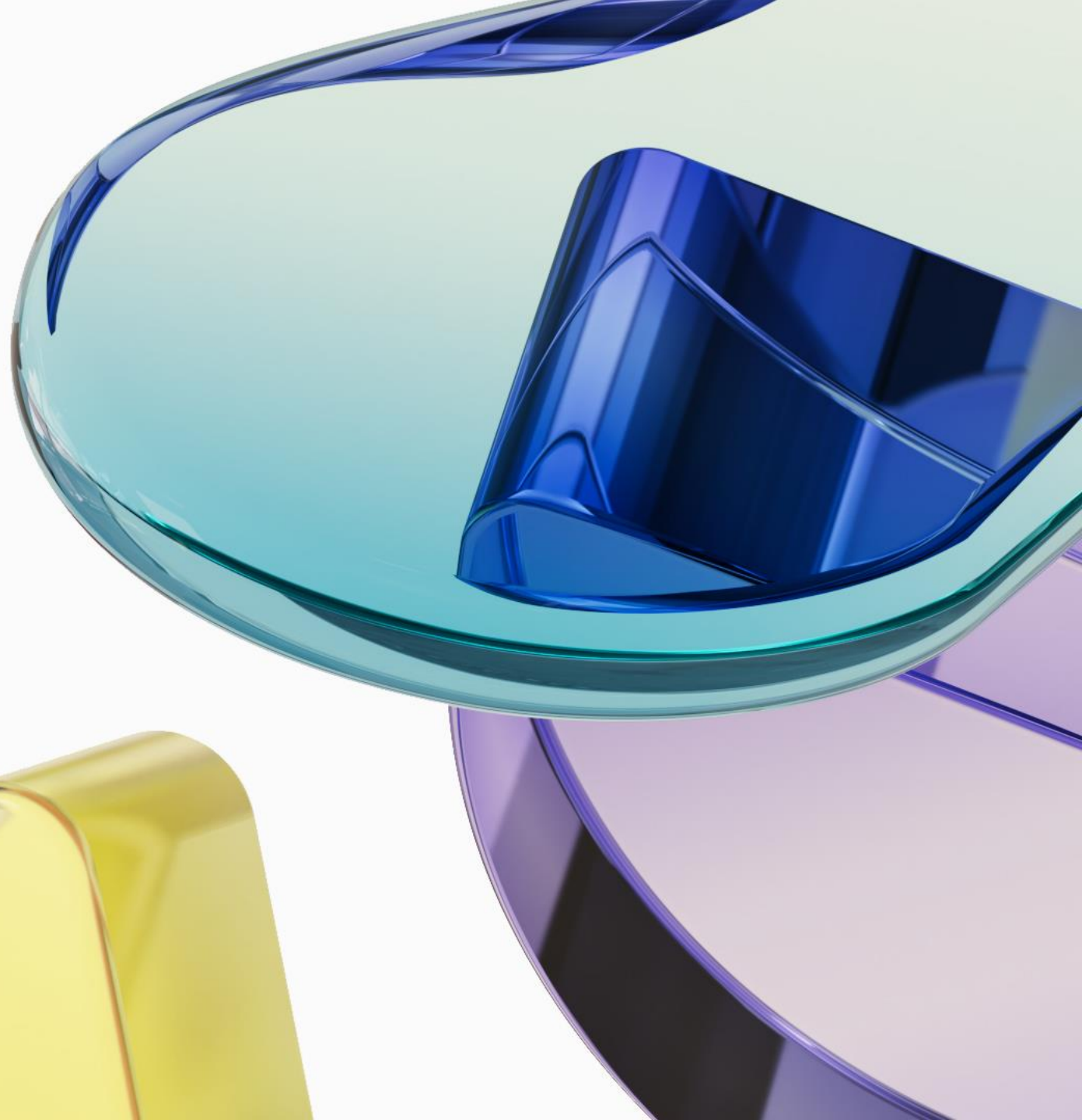
Technical Surveillance Audit

Reporting of changes

Reporting and Assessment of Changes – Manufacturers are required to report all substantial changes to certified products and require amendment of the certificate as appropriate



Typical gaps in submissions



Challenges in the MDSW certification process

Typical gaps in the Technical documentation :

- Intended purpose not clearly defined / too broad.
- Not all requirements have been tested, and no safety class according to EN 62304 is provided(A/B/C).
- Cybersecurity is not / not fully addressed.
- Testing/Usability not conducted with representative users (e.g. clinicians, lay users, etc. as per defined user profile or representative environment)
- Not all known anomalies are documented [A, B, C] and not each anomaly was assessed for risk and justified [B, C]?
- Not sufficient clinical data
- Lack of traceability from requirements to protocols to final test results.



Challenges in the AI MDSW certification process

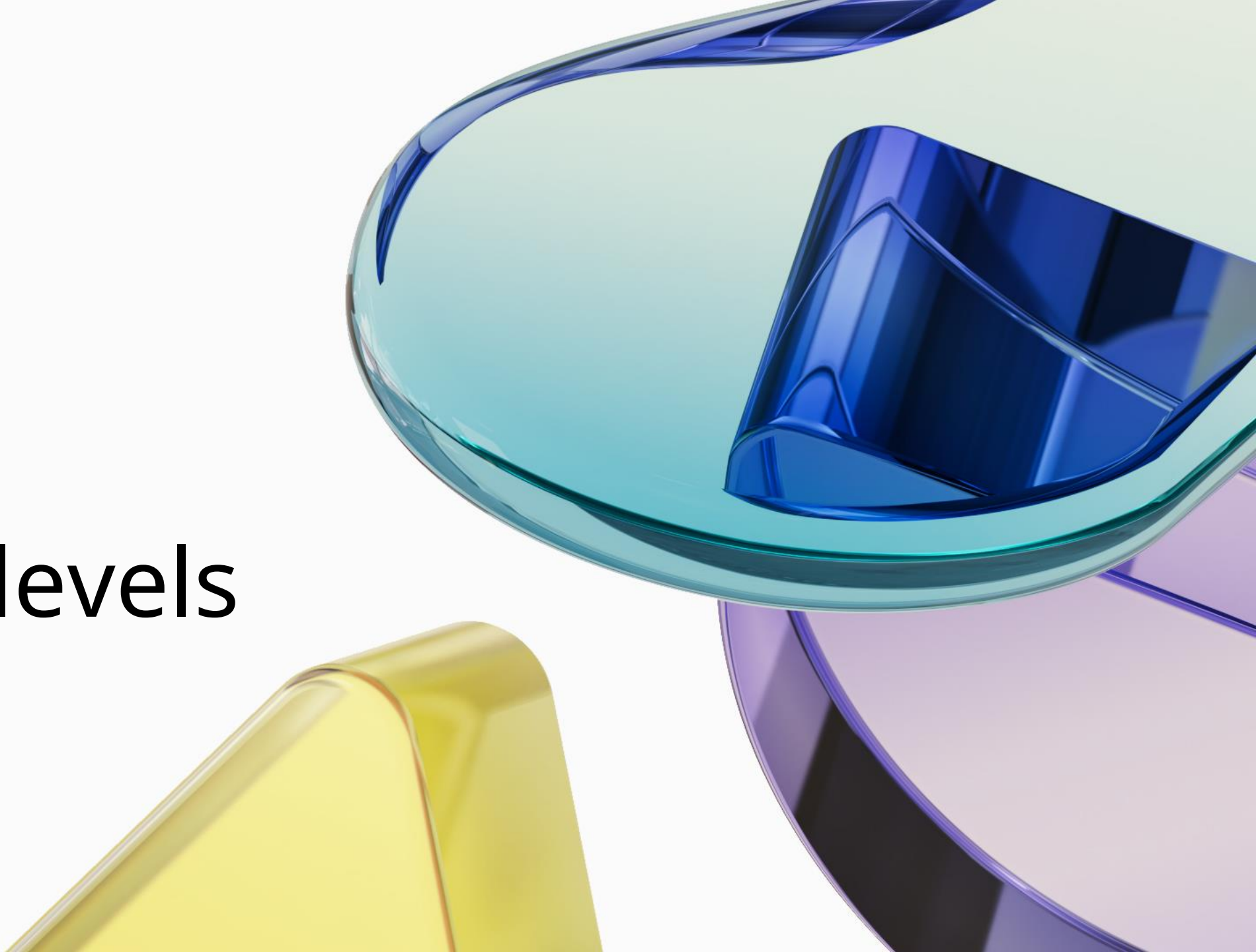
Typical gaps in the AI Technical documentation :

- Lack of transparency in AI models (explainability, Back-box models like deep learning models)
- insufficient data validation : incomplete data sources, bias and quality control of datasets used for training and validation
- Risk management (lack of relevant documents related to AI e/.g: lack of a robust risk management plan to address failure during deployment)
- Generalization of AI model, mostly of the clinical performance of the AI model. Not sufficient evidence provided to support clinical claims.
- Bias and fairness has not been fully validated
- Weak / lacking processes for algorithm life cycle management
- Cybersecurity and data poisoning





Service levels



Predictable and transparent CE marking.

Interactive Dedicated Review

Dedicated interactive reviews foster flexibility, efficiency, predictability and transparency.

This review service consists of a remote technical documentation assessment which is performed interactively between manufacturers and reviewer(s) throughout the assessment to provide a collaborative, transparent and predictable service. The assessment dates, including any follow-up dates required to address open questions are planned and scheduled in agreement with the manufacturer.

This type of review is recommended to be delivered interactively to maximize all the benefits of the service. If the client chooses a less interactive review but still wishes to benefit from pre-scheduling and dedicated reviewer predictability, the review can be delivered fully remotely. There is no additional cost for an interactive dedicated review compared to a non-interactive dedicated review.

CE reviews eligible	All reviews, excluding PSUR and SSCP.
Scheduling of reviews	Pre-scheduled based on expected submission date.
Horizontal reviews	Run in parallel or scheduled to start in advance where consultations are required.
Review coordination, opening and closing meeting	Integrated into the process. All reviews and manufacturer representatives encouraged to participate.
Manufacturer touchpoints	<ul style="list-style-type: none">• Opening/closing meetings. Interactive review integrated into the process.• Real time dialogue during the initial review and after each formal round of questions.• Additional communication by manufacturer or reviewer request.
Initial phase of the review	<ul style="list-style-type: none">• Scheduled window of time (proportional to review duration).• Interactive chat /voice/video via MS Teams.
Rounds of questions	<ul style="list-style-type: none">• Questions/clarifications any time during the initial review.• Formal questions, if needed, sent at the end of the initial review.• Maximum three rounds of questions.
Review question timing	<ul style="list-style-type: none">• Response date aligned between manufacturer and reviewer recommended not to exceed 30 business days.• Responses reviewed once received without undue delay.

Note: Our services do not guarantee an EU/UKCA certificate will be issued or that it will be issued within a certain number of working days but they are based on completing the review process with either a positive or negative recommendation. All type of reviews exclude time under consultation (e.g., Clinical Evaluation Consultation Process - CECP, devices utilizing animal tissue derivatives or medicinal substances which require Competent Authority involvement).



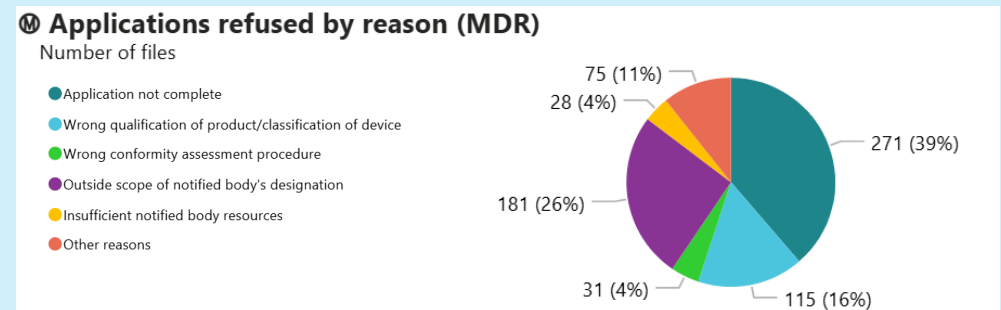
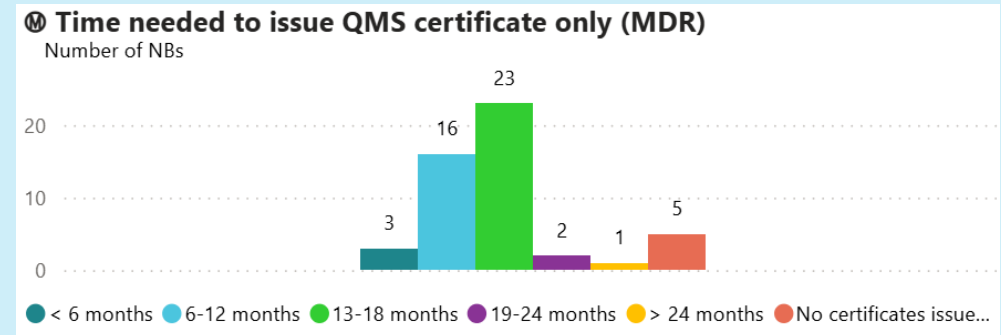
Timelines



Study supporting the monitoring of availability of medical devices on the EU market

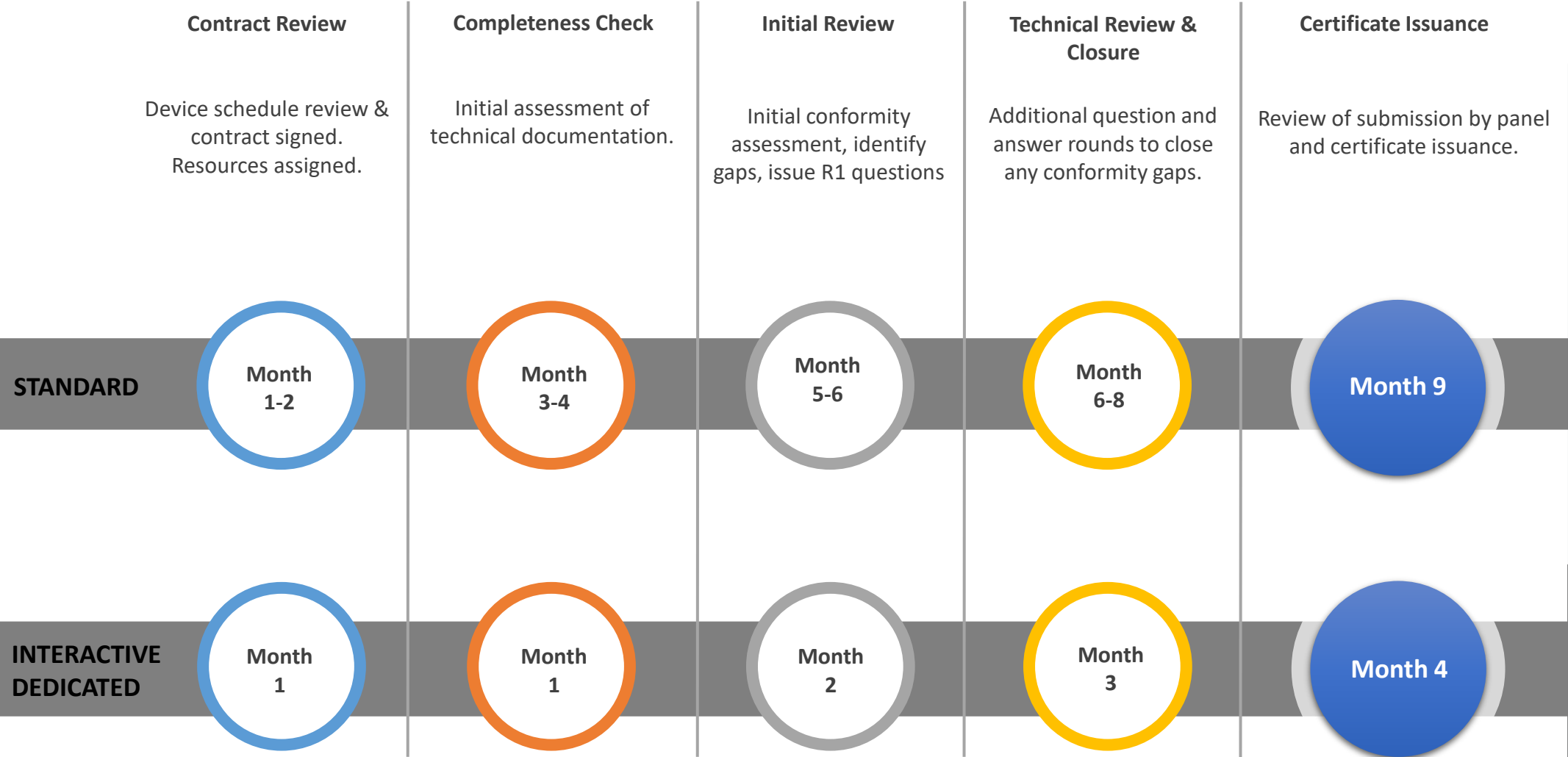
The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - has commissioned a "Study supporting the monitoring of availability of medical devices on the EU market."

The study started in December 2022 and will be running for 36 months (December 2025). The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), in collaboration with Areté and Civic Consulting.



[Study supporting the monitoring of availability of medical devices on the EU market Dashboard](#)

Typical SaMD Initial Application Timelines



This is only applicable if the quality of your technical documentation is high.



Brochures and Whitepapers



10-Step Guide for SaMD Startups



Quick Guide

Placing your SaMD
on the market

A 10 steps guide for Startups

As a Startup working to bring SaMD to market, you must navigate complex regulatory frameworks to ensure your device's safety, performance, and compliance. But where to start from?

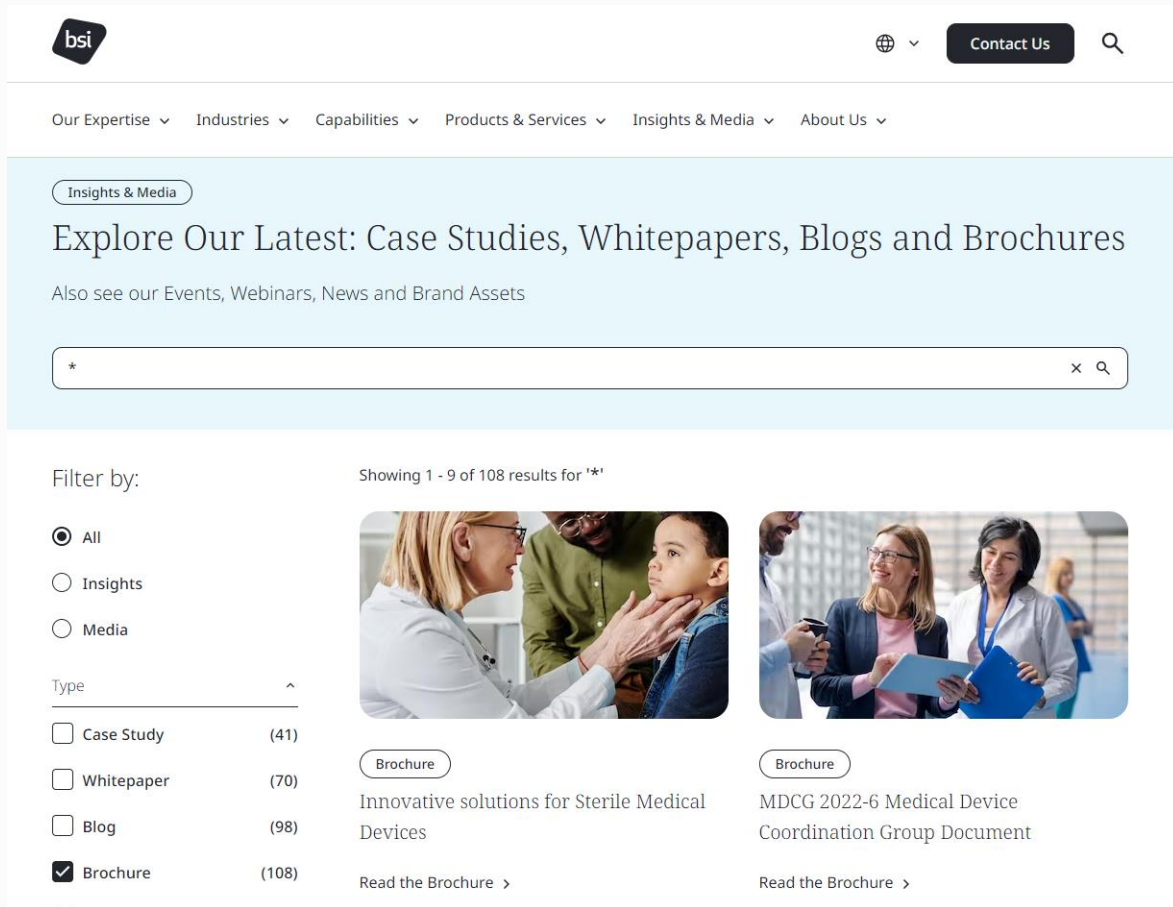
Here is an actionable guide to help you take the first steps to place your SaMD on the market.

- ✓ **Is your software a medical device?**
- ✓ **What is the risk class of your SaMD?**
- ✓ **When is the time to approach a Notified Body? Don't wait!**
- ✓ **Establish a Quality Management System (QMS)**
- ✓ **CE Certification & Documentation**
- ✓ **Clinical Evaluation & Risk Assessment**
- ✓ **Post-Market Surveillance & Vigilance**
- ✓ **Why choose BSI?**
- ✓ **SaMD dedicated Team and expertise**
- ✓ **Deep dive into MedTech regulatory framework and BSI Medical Devices services**

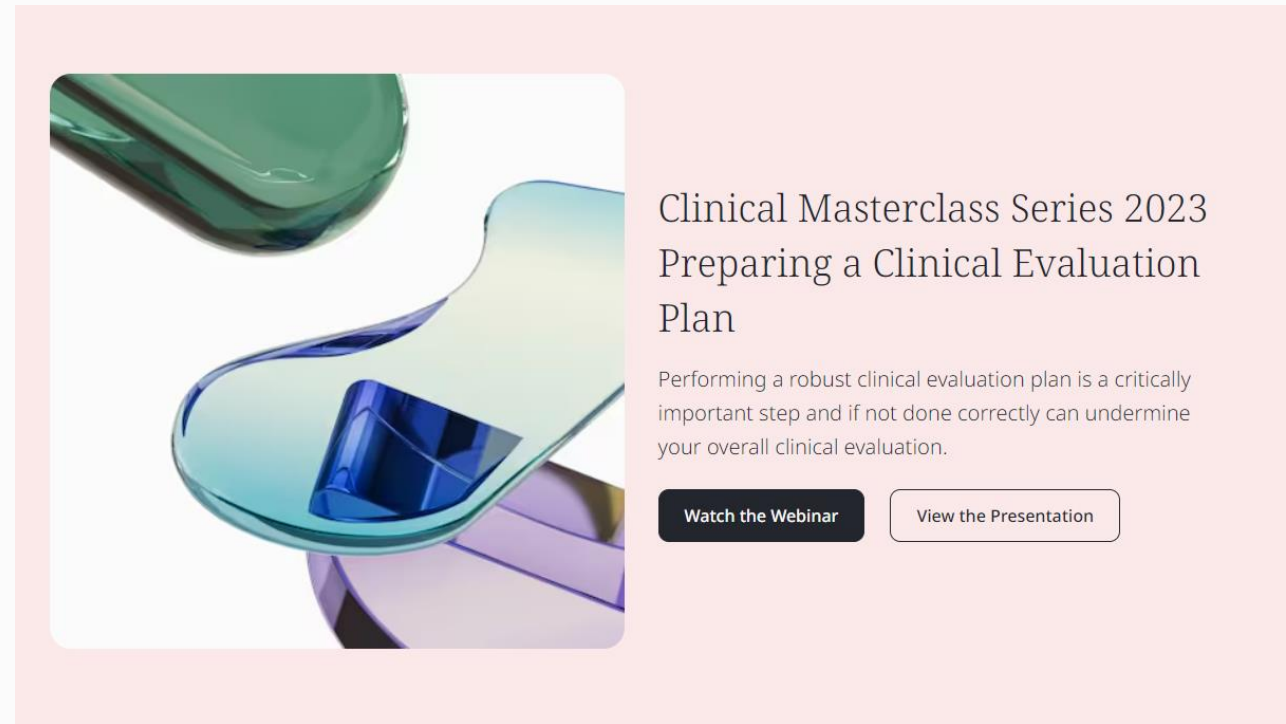


Talk to BSI and start your compliance journey!

BSI Whitepapers, Brochures, Webinars.....

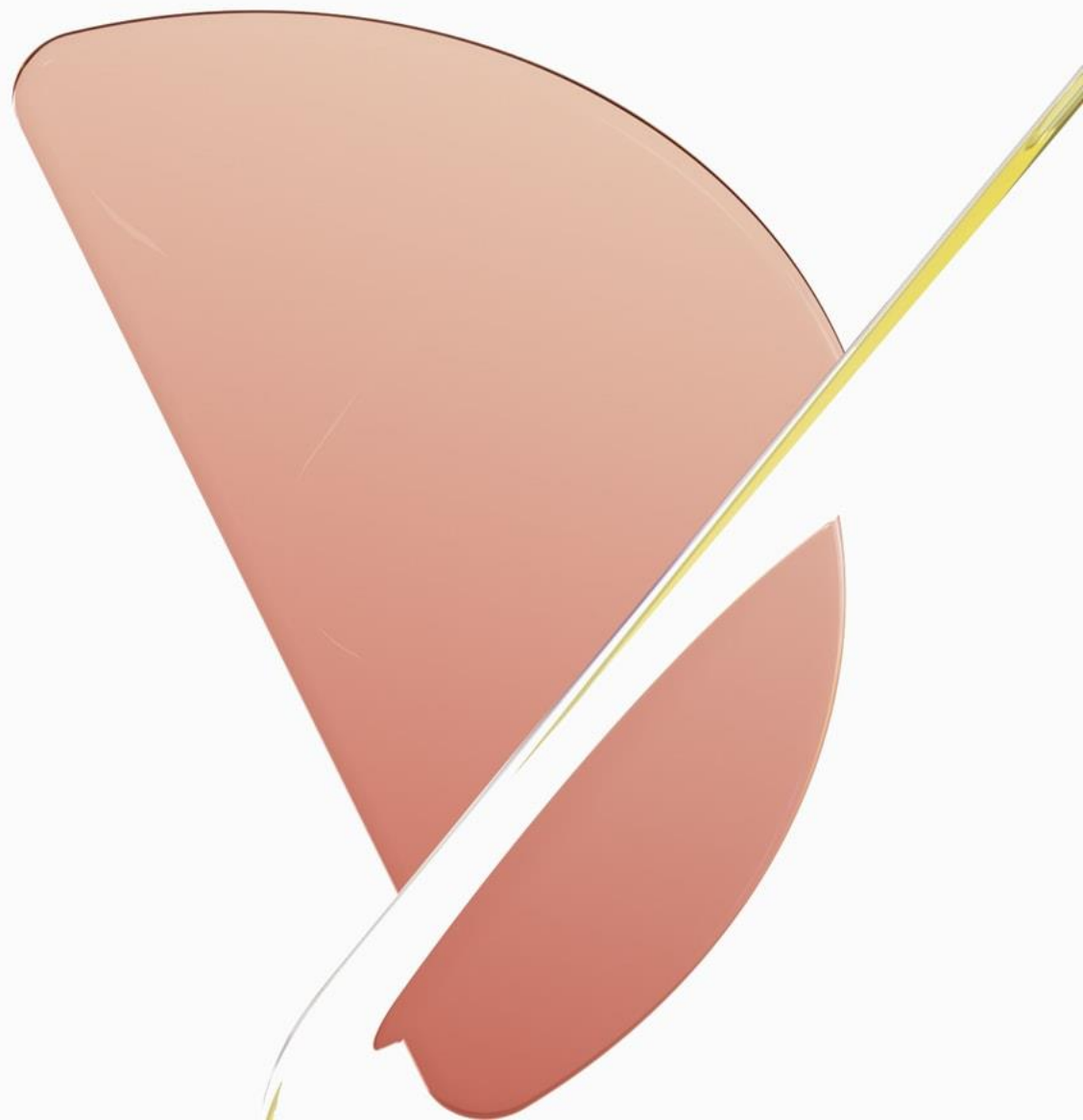


The screenshot shows the BSI website's 'Insights & Media' section. At the top left is the BSI logo. To the right are a globe icon, a 'Contact Us' button, and a search icon. Below this is a navigation menu with 'Our Expertise', 'Industries', 'Capabilities', 'Products & Services', 'Insights & Media', and 'About Us'. The main heading is 'Explore Our Latest: Case Studies, Whitepapers, Blogs and Brochures', with a sub-heading 'Also see our Events, Webinars, News and Brand Assets'. A search bar contains an asterisk. On the left, a 'Filter by:' section includes radio buttons for 'All', 'Insights', and 'Media', and a 'Type' section with checkboxes for 'Case Study (41)', 'Whitepaper (70)', 'Blog (98)', and 'Brochure (108)'. The 'Brochure' filter is selected. The main content area shows 'Showing 1 - 9 of 108 results for '*' and two brochure cards. The first card is titled 'Innovative solutions for Sterile Medical Devices' and the second is 'MDCG 2022-6 Medical Device Coordination Group Document'. Both cards include a 'Read the Brochure >' link.



The banner features a 3D rendering of a blue and green medical device component on the left. On the right, the text reads 'Clinical Masterclass Series 2023 Preparing a Clinical Evaluation Plan'. Below this is a paragraph: 'Performing a robust clinical evaluation plan is a critically important step and if not done correctly can undermine your overall clinical evaluation.' At the bottom right are two buttons: 'Watch the Webinar' and 'View the Presentation'.





Questions?