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A BSI white paper

A Roadmap for SMEs and Startups

Key Steps Towards EU Regulatory Compliance for Medical Devices and In Vitro Diagnostic Medical Devices Manufacturers

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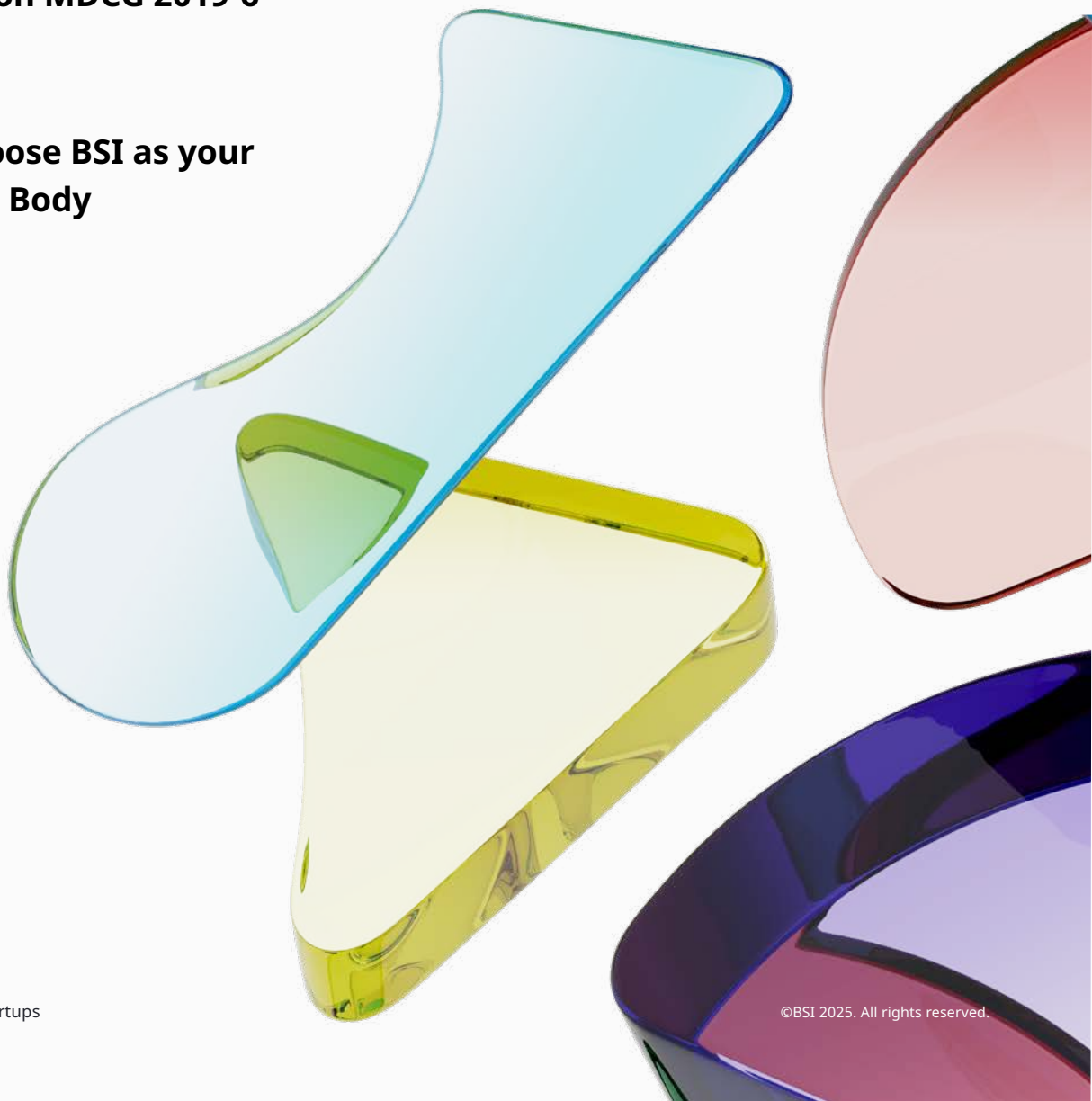
Contents



Introduction

This whitepaper offers guidance for Small and Medium Enterprises (SMEs) and Startups operating in the medical device and in vitro diagnostic (IVD) sectors, with a focus on navigating the European Union's regulatory landscape.

It presents a Notified Body's perspective on the key steps required to achieve regulatory compliance under the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

From initial engagement with the Notified Body through pre-application, formal application, conformity assessment, certification, and post-market surveillance, this roadmap is designed to help understanding expectations and avoid common pitfalls.

SMEs and Startups are vital drivers of healthcare innovation, representing approximately 95%[1] of medical device manufacturers in Europe. Yet, the complexity of EU regulations - combined with limited internal resources - can make compliance a significant challenge. Regulatory deadlines, documentation requirements, and evolving standards often strain smaller organizations, impacting performance and long-term viability.

Despite these challenges, SMEs and Startups play a critical role in addressing unmet clinical needs and advancing technological innovation. Since 2007, EU-funded Startups have raised over €70 billion in venture capital and generated more than €500 billion in enterprise value[2]. Their success depends not only on innovation but on the ability to navigate regulatory frameworks efficiently and strategically.

Note: throughout this paper, when "medical devices" terminology is used, in-vitro diagnostic devices (IVDs) are covered as well, unless specified otherwise.

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[1] MedTech Europe. (2022). The European medical technology industry in figures 2022.

[2] European Commission. (2025). The EU startup and scaleup strategy: Choose Europe to start and scale.

Major challenges

Bringing a medical device or in vitro diagnostic (IVD) device to market in the EU presents a complex set of challenges for SMEs and Startups. These organizations often operate with limited resources, yet must meet the same rigorous regulatory, technical, and commercial standards as larger, established companies. Below is an overview of the key barriers to market entry and growth.

Regulatory compliance

- **Navigating complex and evolving regulations:** MDR and IVDR regulations are subject to frequent updates. Understanding jurisdictional nuances and maintaining compliance across multiple regions can be overwhelming without dedicated regulatory expertise.
- **Clinical and performance evidence requirements:** Demonstrating safety and efficacy through clinical trials or performance studies is often mandatory. These processes are costly, time-intensive, and technically demanding, particularly for novel or high-risk devices.
- **Quality systems and documentation:** Establishing and maintaining a compliant Quality Management System (QMS), such as ISO 13485, alongside compliant technical documentation, is essential. Many SMEs and Startups struggle to allocate the necessary resources to meet these requirements.
- **Approval timelines and delays:** Regulatory reviews can be prolonged, especially when Notified Bodies must consult external agencies (such as Competent Authorities for classification disputes or expert panels) or when documentation is incomplete. Delays can jeopardize funding, partnerships, and market opportunities.

Financial constraints

- **High development costs:** R&D, prototyping, testing, and clinical and performance validation require significant investment. Accessing skilled resources is increasingly competitive, driving up costs and straining budgets.
- **Limited access to Funding:** Securing venture funding or public grants is highly competitive. Early-stage companies often face funding gaps during critical development and regulatory phases.
- **Scaling and market fragmentation:** Transitioning from lab to market and scaling production is capital-intensive. Fragmented regulatory environments and uneven investor interest across regions further complicate growth[3].

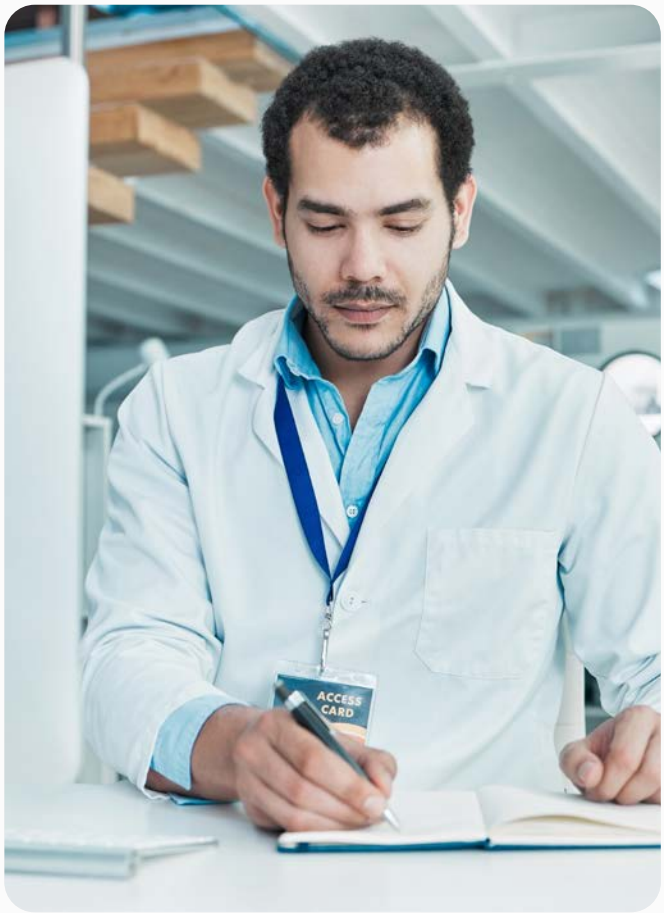
[3] European Commission. (2025). The EU startup and scaleup strategy: Choose Europe to start and scale.

Market access and commercialization

- **Intense competition:** The MedTech landscape is saturated with established players. Differentiating products and gaining market trust is a significant hurdle.
- **Reimbursement complexity:** Securing reimbursement from public and private payers is essential for adoption. Navigating pricing structures and aligning with payer expectations requires strategic planning.
- **Distribution and sales channels:** Building relationships with hospitals, clinics, and distributors is challenging without an established network or commercial infrastructure.

Technical and operational challenges

- **Design and development standards:** Devices must meet stringent safety, usability, and performance criteria. Balancing innovation with compliance is technically demanding.
- **Manufacturing quality:** Achieving consistent, high-quality production processes aligned with regulatory requirements is difficult for organizations with limited manufacturing experience.
- **Post-market Surveillance:** Ongoing monitoring, reporting to Notified Bodies and Competent Authorities regarding incidents, serious events and recalls, require dedicated resources and systems - often lacking in smaller organizations.



Talent acquisition and retention

- **Specialized expertise shortage:** Regulatory, clinical, and manufacturing expertise is in high demand. SMEs and Startups often struggle to attract and retain talent in a competitive market.
- **Scaling teams strategically:** As companies grow, building cross-functional teams with regulatory, clinical, and commercial capabilities becomes increasingly complex.

Risk management

- **Liability and insurance:** Medical devices carry inherent risks. Securing appropriate insurance and managing liability exposure is critical but costly.
- **Supply chain vulnerabilities:** Reliance on external suppliers introduces risk. Disruptions - whether regulatory, economic, or environmental - can impact timelines and product availability.

Time constraints

- **Pressure to innovate quickly:** When it comes to innovative devices, speed-to-market is essential, but regulatory requirements often slow progress. Balancing innovation with compliance is a constant challenge.
- **Approval delays:** Regulatory bottlenecks can delay launches, impacting revenue and investor confidence.

Post-market requirements

- **Serious Incident reporting and follow-up:** Maintaining compliance post-launch requires ongoing vigilance, including reporting serious incidents and conducting post-market clinical follow-up.
- **Product updates and modifications:** Devices may require updates to remain compliant, adapt to new technology or address user feedback. Managing these changes is resource-intensive and technically complex.

Overcoming these challenges

- **Strategic partnerships:** Collaborating with established companies can provide access to expertise, distribution networks, and funding.
- **Outsourcing:** Engaging third-party consultants, Clinical Research Organizations (CROs), and contract manufacturers can streamline operations and reduce internal burden.
- **Targeted funding:** Leveraging grants and innovation-specific funding programmes can ease financial pressure.
- **Innovation and differentiation:** Focusing on unmet clinical needs and clearly articulating device innovation can help gain market traction.
- **Early regulatory engagement:** Proactively engaging with Notified Bodies and Competent Authorities during development helps clarify certification pathways and avoid delays.

Successfully navigating these challenges requires strategic foresight, regulatory literacy, and access to the right partners and resources. With a proactive approach, SMEs and Startups can overcome barriers and bring safe, effective, and compliant medical technologies to market.

Approaching the Notified Body

For SMEs and Startups seeking to bring medical devices or in vitro diagnostic (IVD) products to the EU market, engaging with a Notified Body (NB) is a critical milestone in the regulatory compliance journey.

This process involves understanding the applicable EU legislation, implementing robust compliance systems, and meeting the necessary regulatory requirements to obtain market access.

A structured, proactive approach is essential. This whitepaper, developed by BSI Regulatory Services – Medical Devices, is designed to support SMEs and Startups as they take their first steps toward EU regulatory compliance.

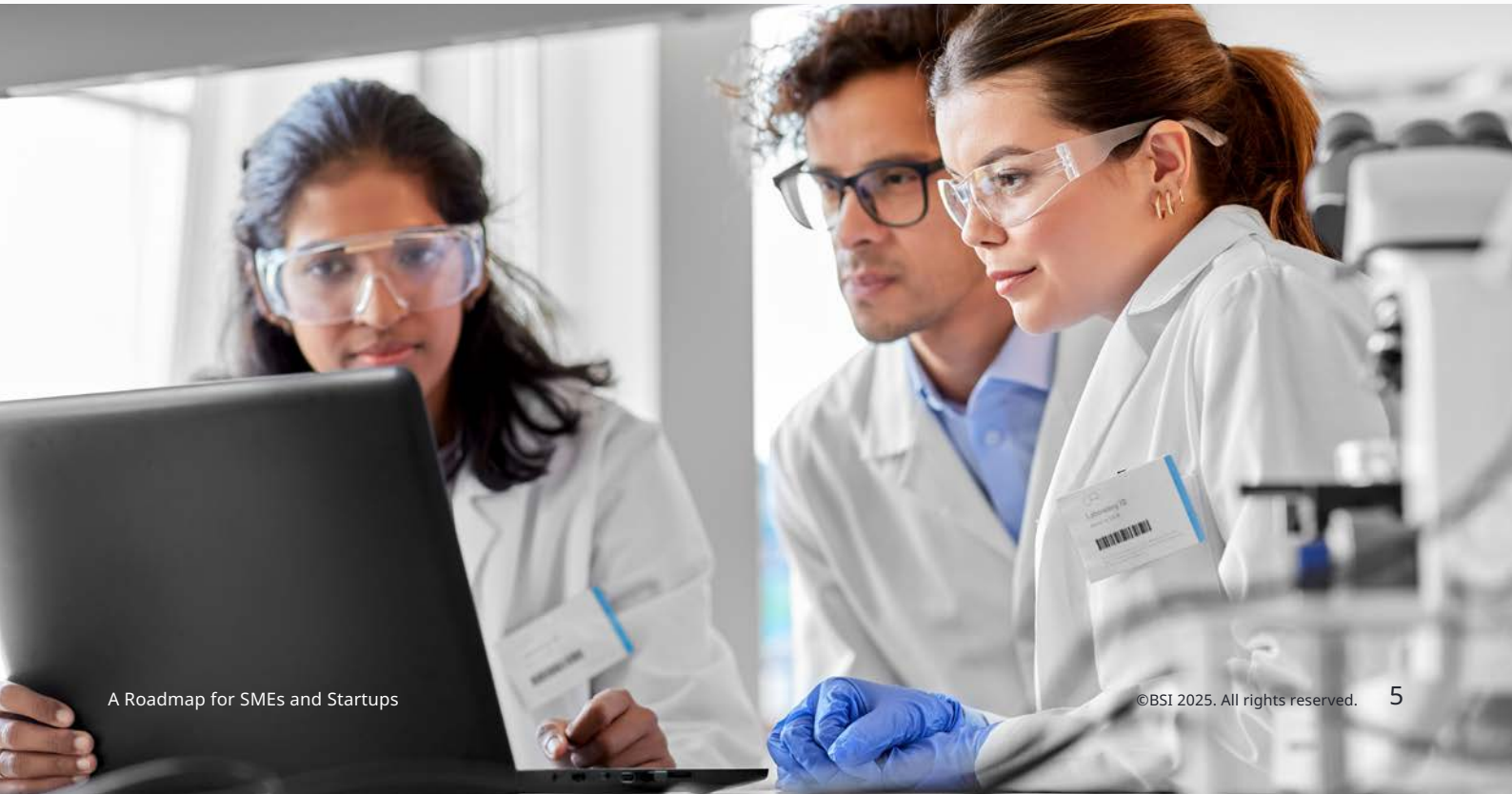
Selecting the right Notified Body

If your device requires a conformity assessment, identifying and engaging with the appropriate Notified Body early in the development cycle is vital. Notified Bodies are organizations designated by EU Member States (or recognized under specific agreements) to assess whether products meet the relevant regulatory requirements before they are placed on the market.

Key considerations when selecting a Notified Body include:

- **Designation scope:** Ensure the NB is designated to issue certificates under the relevant regulation - MDR or IVDR - for the specific device code relevant to your product.
- **Assessment capabilities:** NBs may assess your quality management system (QMS), technical documentation, or both. This may include sampling of devices or full product conformity verification.
- **Certification outcome:** Upon successful assessment, the NB issues a CE certificate, enabling the manufacturer to legally market the device within the EU.

The official list of designated Notified Bodies is available via the **European Commission's Single Market Compliance Space (SMCS)**.



Insight on medical devices codes

To support the designation of NBs and define the scope of conformity assessments, the European Commission established a system of classification codes under the Commission Implementing Regulation (EU) 2017/2185.

These codes (MDA, MDN, MDS, and MDT for medical devices, or IVR, IVS, IVT, IVP and IVD for IVDs) categorize devices based on various factors including design and intended purpose. They are essential in ensuring that NBs possess the necessary expertise to assess types of devices. Understanding and correctly applying these codes is crucial when choosing a NB

Further guidance is provided in MDCG 2019-14 “Explanatory note on MDR codes”, and in MDCG 2021-14 “Explanatory note on IVDR codes”.

TIP

Start early

Begin researching and contacting potential Notified Bodies as early as possible. Understanding their scope, timelines, and cost structures will help you plan effectively and avoid delays.

At the time of publication, BSI was the only Notified Body to have publicly disclosed **lead times for medical device and IVD** certification, a key factor for time-sensitive product launches.

Aligning the product lifecycle with the conformity journey

Approaching a Notified Body requires strategic planning and clear communication. SMEs and Startups should prepare thoroughly to ensure a streamlined assessment process and timely access to market. Below is an overview of key steps to consider, aligned with each stage of the product lifecycle.

Product life cycle stage

Conformity journey

Concept

Initial eveluation of possible development of commercial product

Understanding the regulatory landscape

Step	Action	Details and considerations
Identify applicable Legislation	Determine which EU regulations apply to your device	Review MDR (EU 2017/745) and IVDR (EU 2017/746). Consider additional legislation such as: • Machinery Regulation (EU 2023/1230) • Low Voltage Directive (2014/35/EU) • EMC Directive (2014/30/EU) • RoHS Directive (2011/65/EU) • REACH Regulation (EC 1907/2006) No 1907/2006 • GDPR and EU Product Safety Regulation
Assess territorial requirements	Consider country-specific regulations	While EU regulations apply across member states, some countries may impose additional requirements. Ensure compliance with both EU-wide and national legislation.
Monitor regulatory changes	Stay informed on evolving regulations	Subscribe to newsletters, join industry groups, attend conferences, and monitor official EU websites.
Recommended tools	Use reliable sources for updates	• **BSI Compliance Navigator** • **BSI Medical Devices Newsletter** • **EU Commission Medical Devices Sector Portal**

Device Classification and Conformity Assessment Route

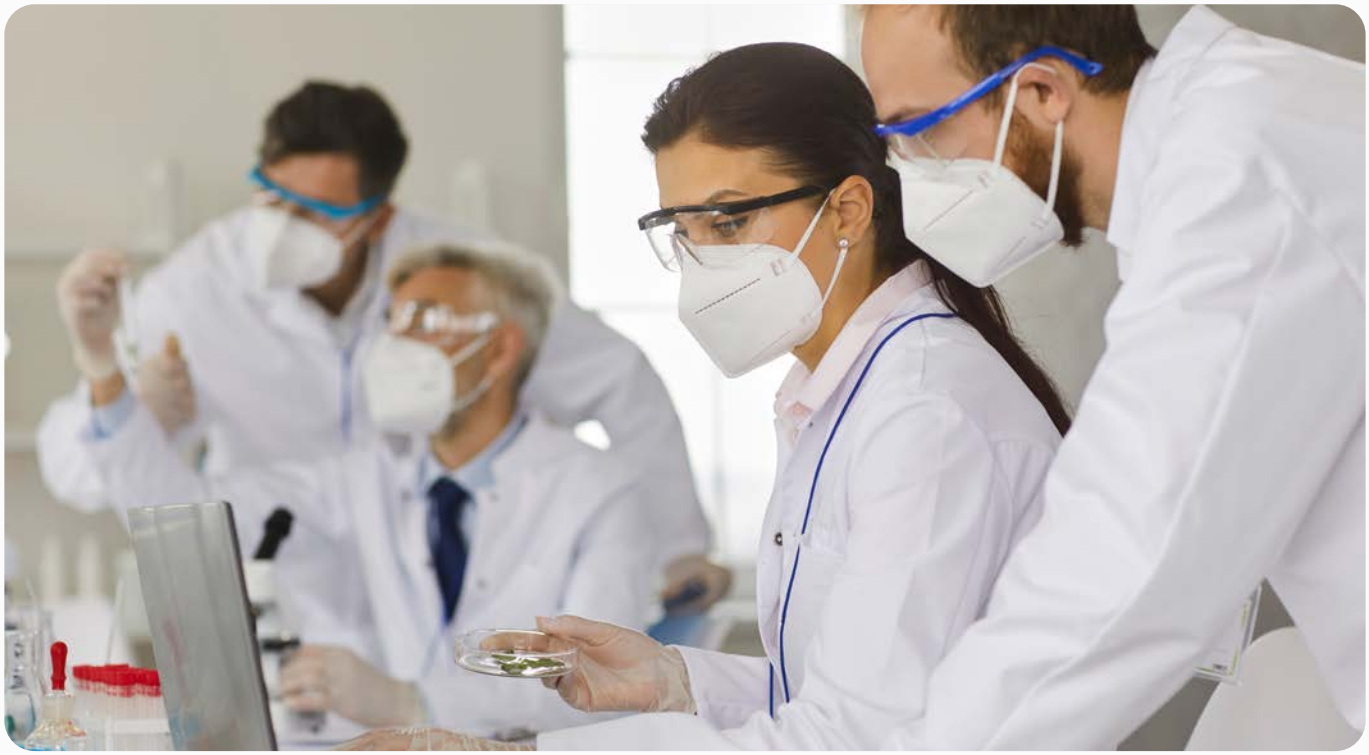
Step	Action	Details and considerations
Confirm Device Type	Verify if your product qualifies as a medical device or IVD	Refer to MDR Article 2(1) and IVDR Articles 2(2) and 2(3) for definitions.
Determine Risk Class	Apply classification rules	Medical Devices: Class I (s-m-r), IIa, IIb, III IVDs: Class A, B, C, D Refer to MDR Article 51 & Annex VIII and IVDR Article 47 & Annex VIII.

Product life cycle stage	Conformity journey		
Concept continued	**Consult Guidance Documents**	Use MDCG resources to interpret and apply classification rules	• **MDCG 2021-24** (Medical Devices) • **MDCG 2020-16** (IVDs) • **MDCG 2019-11** (Software) • **MDCG 2023-5** (Annex XVI devices) • M**DCG 2022-5** and **Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746**
	Conformity Assessment Route	Select the appropriate conformity assessment route	Based on classification, refer to MDR Article 52 and IVDR Article 48. Higher-risk devices require Notified Body involvement.
	Recommended Resources	Use BSI tools for guidance	• **MDR Conformity Assessment Routes** • **IVDR Conformity Assessment Routes**

Product life cycle stage	Conformity journey		
Planning Definition of design input based on customer needs and technical requirements	**Assessing Organizational Resources**		
	Step	**Action**	**Details and considerations**
	Evaluate Internal Capabilities	Assess your team's ability to meet regulatory requirements	Determine whether you have sufficient in-house expertise or need external consultants to support compliance, clinical, and quality activities.
	Define Roles and Responsibilities	Assign clear accountabilities	Establish a compliance structure including roles such as Regulatory Affairs Manager, QA Lead, Legal Advisor, and Technical Expert.
	Appoint a PRRC	Person Responsible for Regulatory Compliance	Required under MDR/IVDR Article 15 and MDCG 2019-7. This individual ensures regulatory obligations are met.
	Appoint a Data Protection Officer (DPO)	Ensure GDPR compliance	If handling large volumes of personal or sensitive data, appoint a DPO. Conduct audits, map data flows, and perform Protection Impact Assessments (DPIA) for new projects impacting personal data.

Implementing Compliant Procedures

Step	Action	Details and considerations
Develop Internal Policies	Establish compliance frameworks	Create policies covering data protection, product safety, QMS, and regulatory obligations.
Deliver Staff Training	Build awareness and accountability	Provide regular training to ensure staff understand and follow compliance procedures.
Maintain Documentation	Record all compliance activities	Keep detailed records to support audits and inspections. Ensure traceability and version control.
Implement a QMS	Align with regulatory standards and requirements	Adopt EN ISO 13485 and meet MDR Article 10(9) / IVDR Article 10(8) requirements. This is often the first review step by Notified Bodies.
TIP	Strategic QMS implementation	Achieving EN ISO 13485 certification is often a prerequisite for securing funding and advancing regulatory approval.
Define Regulatory Strategy	Plan for compliance and certification	Outline how your device will meet all applicable requirements. Prepare for audits and documentation reviews.
Engage with Regulatory Bodies	Maintain proactive communication	Stay connected with Notified Bodies (e.g., BSI) and industry groups (e.g., Team-NB) for updates, guidance, and best practices.



Insight: Leveraging Harmonized Standards for Regulatory Compliance

Harmonized standards are European standards developed by recognized bodies - CEN, CENELEC, or ETSI - at the request of the European Commission. These standards provide a structured and reliable pathway for demonstrating conformity with EU legislation for products, services, and processes.

For medical devices and IVDs, the list of harmonized standards under MDR (EU 2017/745) and IVDR (EU 2017/746) is published in the Official Journal of the European Union (OJEU) and compiled on the European Commission's **website**. Products manufactured in accordance with these standards benefit from a presumption of conformity, simplifying the regulatory process and accelerating market access.

While the use of harmonized standards is voluntary, there are exceptions:

- Mandatory use of symbols or colour codes: Standards such as EN ISO 15223-1 and EN ISO 5359 require strict adherence to specified symbols and colour codes.
- IVDR exemptions for health institutions: Institutions claiming exemptions under IVDR must comply with EN ISO 15189 or relevant national provisions, where applicable.

Adopting harmonized standards not only facilitates smoother conformity assessments but also enhances product quality, safety, and regulatory credibility. For further guidance, refer to MDCG 2021-5: Guidance on Standardization for Medical Devices

Product life cycle stage	Conformity journey

Design

Development of product design and of manufacuring process, verification and validation

Integrating Regulatory Requirements into Product Development

Step	Action	Details and considerations
Embed Compliance in Design	Integrate regulatory requirements early	Conduct pre-market testing, verify safety and performance, and address regulatory concerns during design and development.
Maintain Development Records	Ensure traceability	Document each stage of product development and design to support audits and demonstrate compliance.

Risk Management Strategy

Step	Action	Details and considerations
Conduct Gap Analysis	Identify compliance gaps	Review product and internal processes to highlight areas needing improvement in line with MDR/IVDR.
Initiate Risk Management Early	Build a lifecycle approach	Establish processes for identifying, analysing, and mitigating risks from concept to post-market.

Product life cycle stage	Conformity journey		
Design continued	**Document Risk Controls**	Demonstrate mitigation strategies	Maintain comprehensive risk management documentation to show how device risks are addressed.
	TIP	Use harmonized standards	EN ISO 14971:2019 is the state-of-the-art standard for risk management and is harmonized with MDR and IVDR.

Technical Documentation and Notified Body Engagement

Step	Action	Details and considerations
Prepare Technical Documentation	Align with MDR/IVDR requirements	Include clinical evaluation, risk assessments, labelling, design specs, and manufacturing processes.
TIP	Use best practice guidance	• **Team-NB Best practice guidance for Technical Documentation under the MDR Team-NB Best practice guidance for Technical Documentation under the IVDR** • **BSI Best practice guidance for the submission of Clinical Evaluation documentation** Team-NB offers trainings open to manufacturers: monitor **Team-NB website** and LinkedIn page for training offering. BSI provides a vast offering of free **webinars** and **guidelines**, as well as regional Meet the Experts events to support your compliance journey every step of the way.
Engage early with Notified Body	Initiate pre-application dialogue	Discuss your application scope, timelines, and expectations to align your plan with regulatory requirements.
Pre-Application Topics	Clarify key elements	• Application process • Conformity assessment route • Lead times • Project readiness • Indicative costs

Product life cycle stage	Conformity journey

Validation

Final validation of manufacturing processs and preparation for product introduction

Preparing for Documentation Submission

Step	Action	Details and considerations
Collect Validation & Verification Data	Document testing evidence	Gather all necessary data from validation and verification tests. Ensure results are documented and traceable.
Complete Technical Documentation	Finalize submission materials	Prepare a comprehensive technical file in line with MDR/IVDR requirements. Include clinical evaluation, risk management, labelling, design, and manufacturing details.
Submit to Notified Body	Initiate regulatory review	File your submission with the selected Notified Body unless your product qualifies for self-declaration via an EU Declaration of Conformity.

Conformity Assessment Process

Step	Action	Details and considerations
Provide Initial Information	Share device and process details	Be ready to submit documentation including manufacturing processes, labeling, IFUs, clinical data, risk management files, and supplier details etc.
Undergo Audit and Assessment	Prepare for QMS and technical file review	Notified Body will audit your QMS and assess your technical documentation - including on-site inspections and supplier documentation reviews. Technical documentation assessment can be conducted for each device under application or for at least one representative device per generic device group (for Class IIb and Class C) and for each category of devices (for Class IIa and Class B)
Clarify Timelines	Align expectations	Discuss project timelines and deliverables with the Notified Body to manage internal planning and resource allocation.

Product life cycle stage	Conformity journey

Validation
continued

Prepare for Certification

Step	Action	Details and considerations
Respond to Feedback	Address non-conformities	Be prepared to respond quickly to any findings or requests for additional information from the Notified Body. Timely resolution is critical to avoid delays.
Finalize Certification	Achieve regulatory approval	Once all requirements are met and non-conformities resolved, certification can be granted, allowing market access.

Product life cycle stage	Conformity journey

Launch

CE Certification and Marking

Step	Action	Details and considerations
Receive CE Certification	Final approval from Notified Body	Once conformity is confirmed, the Notified Body issues a CE Certificate, allowing the device to be legally marketed in the EU.
Affix CE Mark	Ensure correct labelling	CE marking must be correctly applied to the product and packaging. Ensure supporting documentation (e.g., signed Declaration of Conformity) is available and compliant.

Product life cycle stage	Conformity journey

Post-market

Product Performance monitoring

Step	Action	Details and considerations
Monitor Product Performance	Implement surveillance systems	Collect user feedback, monitor safety, and address non-compliances. Maintain ongoing compliance with EU legislation.
Meet Reporting Obligations	Fulfil legal requirements	Submit reports on serious incidents, field safety corrective actions, and trend analyses. Prepare for potential recalls or safety notices.

Audits and inspections

Step	Action	Details and considerations
Prepare for External Audits	Maintain readiness	Notified Bodies and Competent Authorities may conduct follow-up audits or inspections. Keep QMS and documentation up to date.
Conduct Internal Audits	Review and refine processes	Regularly audit internal systems to identify gaps and ensure alignment with evolving regulations. Use feedback from audits and surveillance to improve compliance.
TIP	Compliance is continuous	Regulatory compliance is not a one-time event. Establish a culture of ongoing review and improvement.

Penalties and enforcement

Step	Action	Details and considerations
Understand Legal Risks	Be aware of consequences	Non-compliance can result in fines, reputational damage, and enforcement actions - especially for data protection, safety, and consumer rights violations.
Create a Contingency Plan	Respond to breaches effectively	Develop a plan to address compliance breaches, notify affected parties, and implement corrective actions swiftly.
Maintain Vigilance	Fulfil post-market obligations	Continue to meet requirements for vigilance, incident reporting, and documentation maintenance as part of your regulatory responsibilities.

Additional considerations when engaging a Notified Body

To ensure a smooth and efficient conformity assessment process, SMEs and Startups should factor in several strategic and operational elements:

Cost and time planning
Notified Bodies may apply variable fee structures depending on the complexity, classification, and risk class of your device. It is essential to request a detailed quote early in the process - one that includes all stages of assessment, including potential rounds of technical queries. The process can be both time-consuming and financially demanding, particularly for resource-constrained organizations. Budgeting for both time and cost is critical to avoid delays or disruptions.

Certain device types require additional regulatory involvement:

- **Devices incorporating medicinal substances, human or animal origin materials, or Companion Diagnostics (cdx)** must involve the European Medicines Agency (EMA) or relevant national competent authorities.
- **High-risk devices (e.g., Class III implantables)** may require a clinical/performance evaluation consultation procedure under MDR Article 54 or IVDR Article 48(6).
- **Class D IVDs** must undergo performance verification by an EU Reference Laboratory (EURL), as outlined in IVDR Article 48, including batch release testing post-certification.

These additional steps should be factored into your overall regulatory timeline and cost projections.

Build strategic relationships
Establishing a transparent and collaborative relationship with your chosen Notified Body can significantly improve communication and streamline the assessment process. While NBs are legally prohibited from consulting on specific product matters, openness and clarity in your submissions foster trust and efficiency.

Leverage External Expertise
If your internal team lacks regulatory experience, consider engaging a qualified regulatory consultant. These experts can help prepare your documentation, guide you through audits, and ensure readiness for assessment. While Notified Bodies cannot provide product-specific advice, external consultants can bridge knowledge gaps and support your compliance strategy.

Key Takeaways for SMEs and Startups

- Understand the applicable regulations and select a Notified Body designated for your device type and classification.
- Engage early with a NB to clarify scope, timelines, and fees, and to align your development compliance journey with regulatory requirements and NB expectations. Make use of **BSI's Structured Dialogue**.
- Prepare your QMS and technical documentation thoroughly before submission.
- Ensure quality and traceability through robust QMS and technical documentation. Plan for audits and respond promptly to queries and non-conformities.
- Maintain compliance post-certification through proactive ongoing surveillance, and post-market requirements.

Reasons for delays in conformity assessments

The implementation of the MDR and IVDR has introduced significant challenges across the MedTech sector. While large manufacturers have faced increased complexity, SMEs and Startups have been disproportionately affected due to limited resources and regulatory experience.

Common concerns include rising compliance costs, global competition, lack of timely guidance, and difficulty adapting to evolving regulatory expectations. Notified Bodies have often been criticized due to the consequent extended timelines in issuing CE certificates. However, many delays stem from issues outside the Notified Body's control - primarily related to the quality and completeness of submissions.

Common pitfalls

Incomplete or inadequate risk management documentation

Risk management is central to demonstrating device safety and performance. Submissions lacking comprehensive risk analysis - covering hazard identification, risk evaluation, control measures, and post-market surveillance - can significantly delay the conformity assessment. A comprehensive design and process risk management assessment should be performed throughout the entire lifecycle of the device, from the initial design concept to its disposal. Aligning documentation with the latest version of ISO 14971, harmonized under MDR and IVDR, is strongly recommended.

Insufficient clinical or performance evidence

For high-risk devices, robust clinical data is essential. Delays often arise from weak or incomplete Clinical Evaluation Reports (CER) or Performance Evaluation Reports (PER). These should include sufficient clinical data including studies, literature reviews, and post-market data where applicable.

Failure to meet regulatory requirements or standards

Non-compliance with MDR/IVDR requirements or relevant standards can halt progress. Manufacturers must stay current with regulatory updates, apply the correct harmonized standards, and ensure full alignment across requirements related to product classification, labelling, and instructions for use etc.

Non-compliant Post-Market Surveillance (PMS) and vigilance planning

A lack of documented PMS and vigilance systems - especially in the face of emerging incidents - can trigger delays. A robust PMS Plan should include performance monitoring, incident reporting, and corrective action procedures.

Inadequate device description and specifications

Unclear or incomplete device descriptions and intended use can lead to misclassification or confusion during the conformity assessment. Provide detailed information on intended use, design, materials, and functional specifications to support an accurate evaluation from the NB.

Poorly documented manufacturing processes

Manufacturing and quality processes documentation must clearly outline production methods, quality control procedures, and compliance with relevant standards. Gaps or inconsistencies in this area can stall the review process.

Disorganized or inconsistent technical documentation

Technical files that are incomplete, poorly structured, or internally inconsistent are a common source of delay. Ensure documentation is comprehensive and well-organized, covering all required elements per MDR/IVDR Annex II and III.

Unclear or non-compliant labelling and Instructions for Use (IFU)

Labelling and IFUs must meet the requirements of Annex I, Section 23 of MDR/IVDR. They should be clear, accurate, and provide all necessary information for safe and effective use, including warnings, precautions, and disposal instructions.

Failure to update documentation following design changes

Any changes to device design, manufacturing processes, or regulatory context must be reflected in updated documentation. Failure to do so can result in discrepancies that delay or invalidate the conformity assessment.

Inadequate or missing biocompatibility data

Demonstrating biocompatibility and safety of the device materials is essential, especially for devices that come into direct contact with the human body. Failure to provide a biological safety risk assessment or conduct appropriate testing - aligned with ISO 10993 - can result in significant delays. Ensure that all relevant biocompatibility data is included and clearly documented.

Insufficient clinical or performance testing data

Clinical and performance validation is critical to prove device functionality, accuracy, and reliability. Lack of thorough testing data, especially for high-risk or novel devices, can stall the conformity assessment. Testing protocols should be designed to reflect the device's intended use and meet the requirements outlined in Annex XIII (IVDR) and Annex XIV (MDR).

Poor communication and coordination with the Notified Body

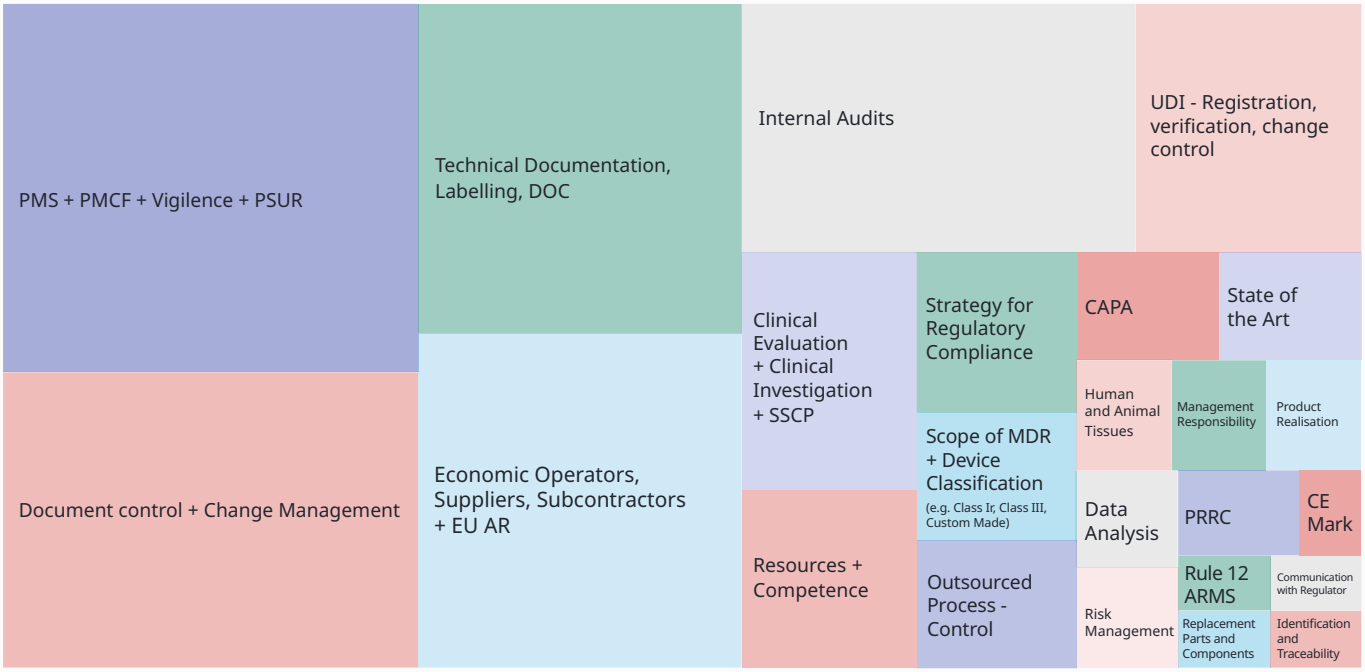
Misalignment or delayed responses to Notified Body queries can disrupt the review schedule. Maintain proactive, transparent communication throughout the process. Respond promptly to requests for clarification and ensure all documentation is submitted according to the agreed timeline. Adhering to the review schedule set at the time of initial application is essential to avoid bottlenecks.

Non-conformities: a Notified Body perspective

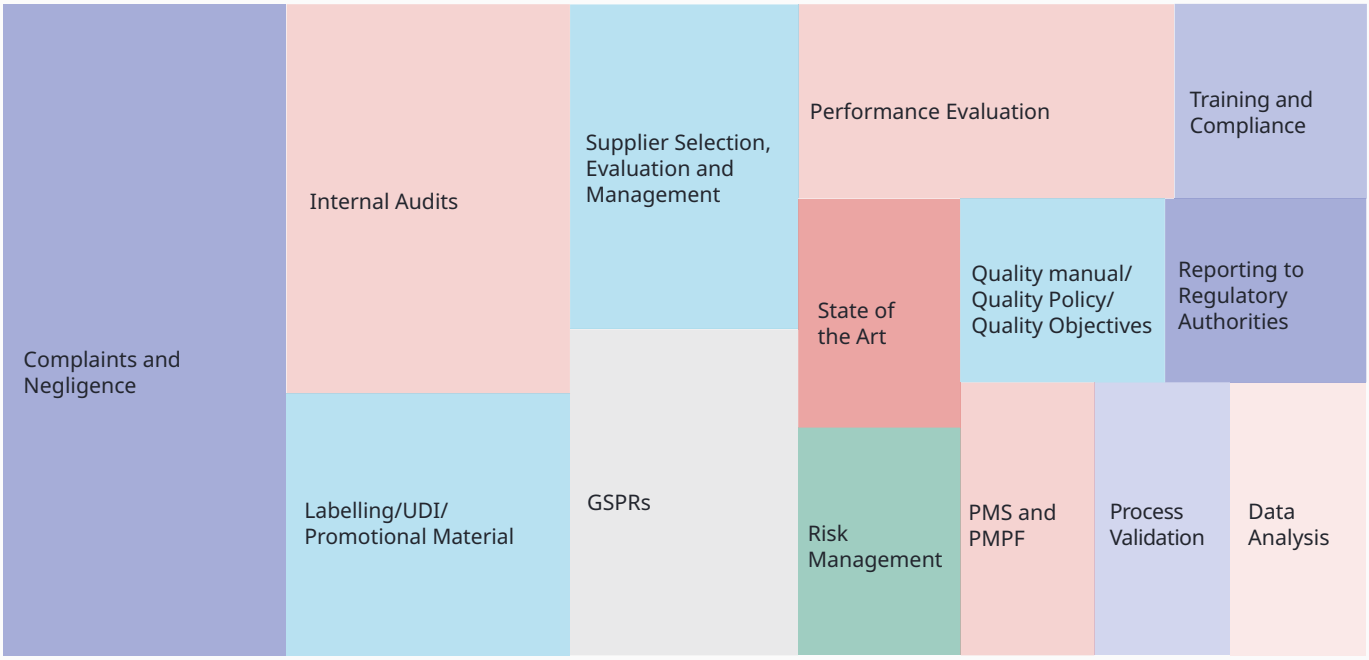
Drawing on decades of experience in device and QMS certification, BSI has identified recurring areas of non-conformity under MDR and IVDR. These findings are based on documentation reviews and audits conducted up to 2024. The bigger the dimension of the box, the higher the occurrence of the non-conformity displayed.

Non-conformities raised during QMS audit

MDR

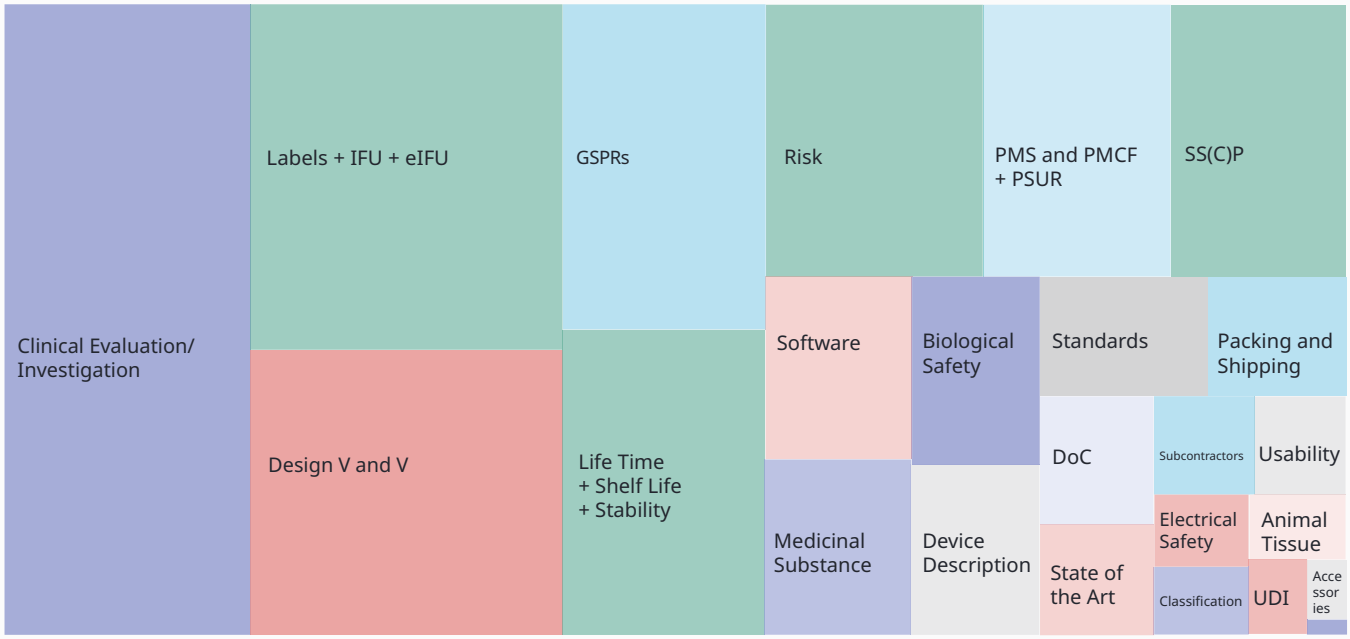


IVDR

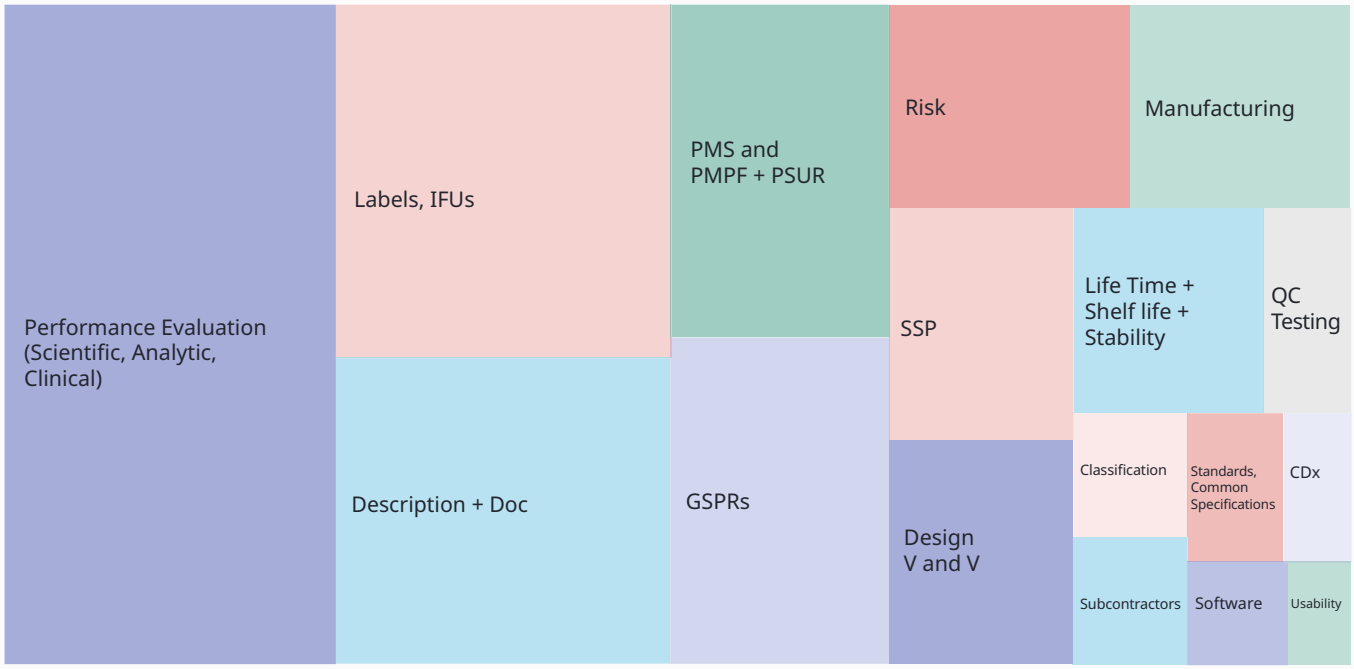


Non-conformities raised during technical documentation review

MDR



IVDR



The prevalence of these issues underscores the importance of early planning, internal alignment, and regulatory expertise. By addressing these areas proactively, SMEs and Startups can significantly reduce delays and improve the likelihood of a successful conformity assessment.

Avoiding these pitfalls requires early planning, internal alignment, and a commitment to regulatory excellence. Investing in documentation quality, risk management, and clinical validation not only enhances the conformity assessment process but also strengthens market readiness and investor confidence.

A focus on MDCG 2019-6 Rev. 5

For SMEs and Startups navigating the EU regulatory landscape, **MDCG 2019-6 Rev. 5**, - *Questions and Answers: Requirements relating to Notified Bodies* - serves as a critical resource. Issued by the Medical Device Coordination Group (MDCG), this guidance document provides clear, practical insights into the role and expectations of Notified Bodies under the MDR and IVDR frameworks.

Clarifying Notified Body requirements

One of the most significant challenges for smaller organizations is understanding the role of Notified Bodies. MDCG 2019-6 clarifies how Notified Bodies operate, what they assess, and how manufacturers should prepare.

Streamlining the certification process

The document outlines the key steps in the conformity assessment process, including timelines, documentation requirements, and procedural expectations. For SMEs and Startups, this clarity is essential to avoid missteps that could lead to delays, non-conformities, or rejection. By following the guidance, companies can better align their internal processes with regulatory expectations.

Understanding NB audits and inspections

MDCG 2019-6 Rev. 5 provides valuable insight into how Notified Bodies conduct audits and review technical documentation. It explains what auditors look for and how technical documentation assessments are structured. This enables manufacturers to prepare more effectively, reducing the risk of failed audits and costly remediation.

Compliance expectations made clear

For organizations with limited regulatory expertise, the document offers a clear breakdown of what is expected during the certification process. Understanding these expectations from the outset allows SMEs and Startups to build compliant systems and avoid reactive corrections.

Supporting transition from legacy directives

Companies transitioning from the previous Directives (MDD, IVDD, AIMDD) to MDR or IVDR will find the guidance particularly useful. MDCG 2019-6 Rev. 5 highlights key differences in regulatory requirements and helps manufacturers adjust their documentation and processes to meet the more stringent criteria of the regulations.

Cost-effective regulatory support

For SMEs and Startups with limited budgets, hiring external consultants for every regulatory question may not be feasible. MDCG 2019-6 Rev. 5 reduces this dependency by offering authoritative answers to frequent questions regarding notified bodies' role, helping organizations make informed decisions without incurring unnecessary costs.

Building confidence in the regulatory process

By demystifying the role of Notified Bodies and offering practical guidance, the document empowers SMEs and Startups to engage with greater confidence. A clearer understanding of the process leads to better preparation, smoother interactions, and faster access to market.

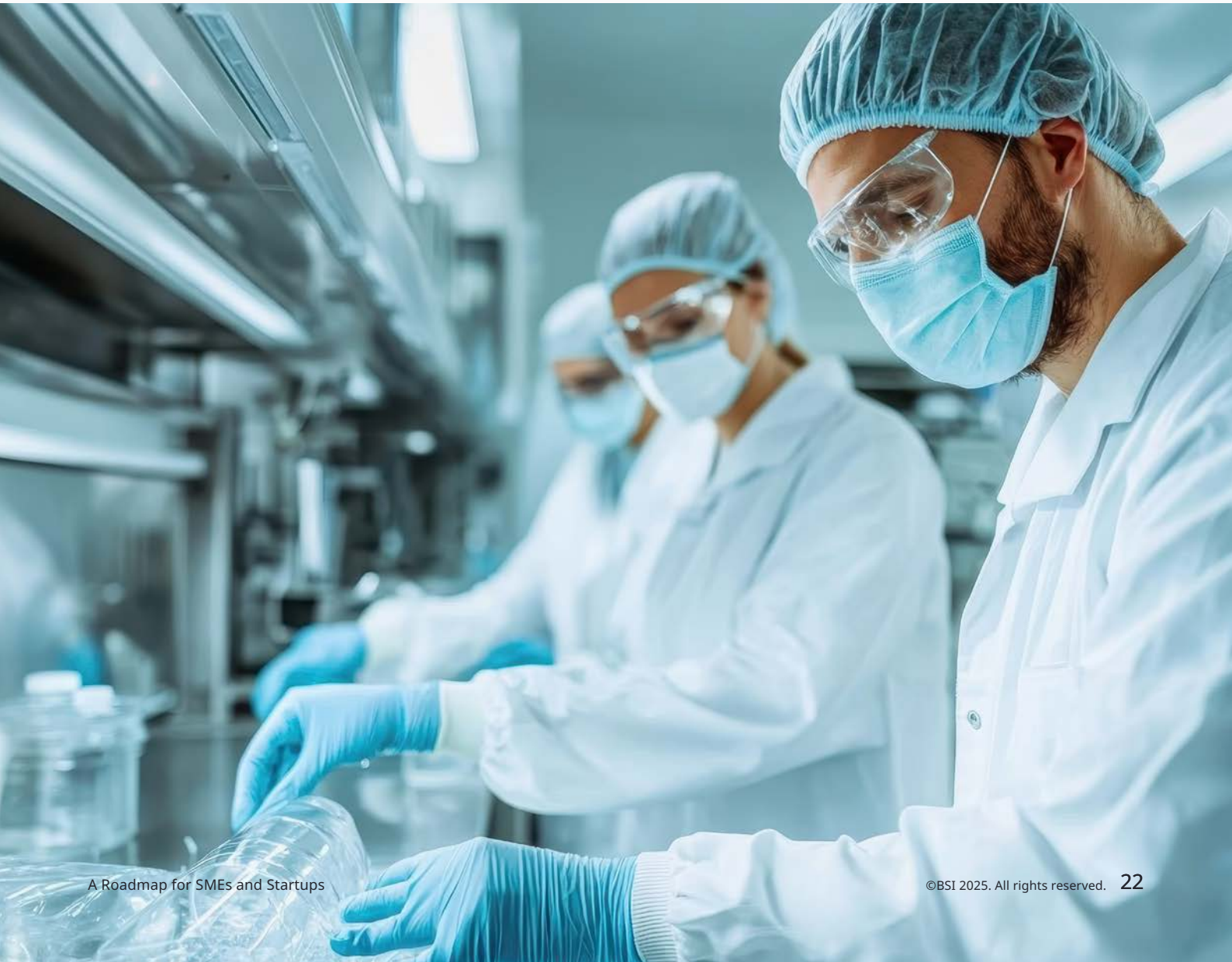
Guidance on specific scenarios

The document also addresses nuanced situations that SMEs and Startups may encounter, such as:

- Working with non-EU manufacturers;
- Updating previously certified devices;
- Navigating complex device classifications.

These insights help organizations remain compliant even in less straightforward regulatory scenarios.

In summary, MDCG 2019-6 Rev. 5 offers valuable support to SMEs and Startups. It provides clarity, reduces uncertainty, and supports cost-effective compliance with MDR and IVDR. By leveraging this guidance, organizations can streamline their engagement with Notified Bodies a and navigatetheir compliance path towards EU market access.

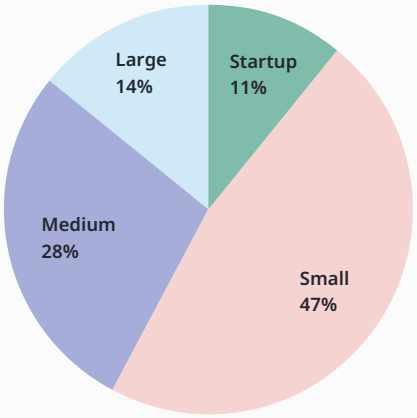


Why choose BSI as your Notified Body

BSI is a globally recognized full scope Notified Body and UK Approved Body with decades of experience in the medical devices sector. Our reputation is built on a foundation of independence, transparency, and efficiency - qualities that are especially critical for SMEs and Startups navigating the complexities of MDR and IVDR compliance.

We have successfully delivered thousands of certifications under MDR and IVDR, supported by a team of highly qualified regulatory, clinical, and technical experts. **Today, over 86% of the manufacturers we work with are SMEs, and 11% are Startups**, reflecting our deep commitment to supporting innovation and early-stage growth in the MedTech sector.

BSI understands the unique challenges SMEs and Startups face - from limited resources and regulatory uncertainty to time-sensitive market entry. We continue to accept new applications and actively refine our tools and processes to better support smaller organizations. Our goal is to help you move confidently through the conformity assessment process and bring safe, compliant medical devices to patients.



Our support in numbers

- More than 2000 MDR certificates issued.
- More than 500 IVDR certificates issued.
- 86% of clients are SMEs.
- 11% are Startups.
- Transparent and monthly updated **conformity assessment lead times**.

Comprehensive Resources to Support Your Compliance Journey

BSI offers a wide range of **services** to help SMEs and Startups build regulatory knowledge and readiness:

Structured Dialogue

Engage with BSI early to clarify your regulatory pathway, understand timelines, and align expectations. **Structured Dialogue** helps reduce uncertainty and supports efficient planning.

Newsletter

Stay informed with our monthly Medical Devices Newsletter, featuring updates on regulations, standards, quality systems, and industry trends.

Sign up to our Medical Devices Newsletter **here**.

Webinars

Access our portfolio of on-demand and live webinars led by BSI's technical, regulatory, and clinical experts. Topics include MDR/IVDR requirements, market access, and QMS implementation.

Explore webinars **here**.

Training Academy

Deepen your regulatory expertise with specialized training courses covering medical devices, IVDs, and quality management systems. Courses are delivered by global industry experts.

Access training **here**.

Compliance Navigator

A powerful digital platform that helps monitor your organization's compliance against over 6,000 regulatory documents. Features include regulatory profiles, expert commentary, alerts, and intelligent search.

Learn more **here**.

Whitepapers and guidelines

Access a comprehensive library of free whitepapers and guidelines authored by BSI subject matter experts. Topics include clinical investigations, surveillance, standards, and best practices.

Download our whitepapers **here**.
Download our guidelines **here**.

Working with BSI means more than certification - it means gaining an independent and trusted expert committed to your progress.

Get in touch

Whether you are preparing for your first submission, transferring from another Notified Body, or scaling your regulatory capabilities, BSI offers the expertise, tools, and support to help you succeed.

Talk to us

Organizations supporting SMEs and Startups

Navigating the regulatory landscape of the medical device and IVD sectors can be particularly challenging for SMEs and Startups. A wide network of organizations and initiatives exists to support early-stage companies with funding, mentorship, regulatory guidance, and market access. Below is a curated list of key organizations offering support across the EU and globally.

European-Based Support

Horizon Europe
The EU Commission research and innovation programme offers substantial funding for SMEs and Startups developing innovative healthcare technologies.

- Grant funding for R&D projects;
- Collaborative opportunities with other European organizations and businesses;
- Focused on innovative technologies and projects in the healthcare sector.

InvestEU
A major EU Commission initiative supporting companies at all stages of development.

- Seed capital and scale-up support;
- Manufacturing and deployment funding;
- Strategic backing for high-growth ventures.

Enterprise Europe Network
Provides targeted regulatory support and raises awareness on regulatory requirements for SMEs in the medical device sector.

EU4Health Programme
Enhances financial support and preparedness for SMEs, facilitating smoother access to the EU market.

EU Startup and Scaleup Strategy
Aims to transform Europe into a global innovation leader by improving access to capital, talent, and markets, while reducing regulatory fragmentation.

European Medical Device National Business Organizations (NBOs)
Country-specific organizations offer regulatory guidance, funding, and networking tailored to local market conditions.

Global and Regional Support Initiatives

The International Medical Device Regulators Forum (IMDRF)
Voluntary group of medical devices regulatory authorities working on harmonizing international regulatory requirements and standards.

Small Business Administration (SBA – USA)
Supports small businesses with loans, grants, and export assistance, plus:

- Access to capital;
- Mentorship and advisory services;
- International market entry support.

National Institutes of Health (NIH) – SBIR Programme
Provides research grants for early-stage innovation in medical devices and diagnostics, including:

- Funding for healthcare-focused Startups;
- Commercialization support;
- Innovation acceleration.

Health Technology Exchange (HTX – Canada)
Supports Canadian SMEs with market access and innovation resources, specifically:

- Industry networking;
- Commercialization support;
- Business development tools.

BioM – Munich Cluster for Health and Medical Technology (Germany)
A regional accelerator supporting biotech and MedTech companies, including:

- Market entry assistance;
- Investor networking;

Business development support.

Industry Networks and Accelerators

StartUp Health
A global innovation network offering funding, mentorship, and strategic growth opportunities, including:

- Entrepreneurial support;
- Access to healthcare experts;
- Investment capital.

Health 2.0
Connects health-tech Startups with investors, healthcare systems, and strategic partners, specifically through:

- Exposure through events and partnerships;
- And a community of innovators and investors.

Plug and Play Health
A global accelerator linking Startups with industry leaders and investors, including:

- Strategic partnerships;
- Growth mentorship;
- Funding access.

MassChallenge HealthTech
Supports healthtech Startups with mentorship, funding, and industry connections, with:

- Global reach;
- Access to healthcare leaders;
- Commercialization support.

BioEnterprise
An accelerator focused on healthcare innovation through:

- Investment and mentorship;
- Business development resources;
- Commercialization pathways.

Medical Device Manufacturers Association (MDMA)
Advocates for innovative SMEs and Startups in the medical device sector, including:

- Regulatory education;
- Policy advocacy;
- Networking opportunities.

Additional guidance resources

- **Enterprise Europe Network** raises awareness of regulatory requirements and provides targeted support.
- **Factsheet Health European Union** Outlines short- and long-term actions to support the transition to MDR/IVDR.
- **EU4Health Programme** promotes financial support, facilitates access, and supports preparation of SMEs.
- **The European Commission Q&A** Clarifies transitional provisions for MDR/IVDR compliance.
- **EU Startup and Scaleup strategy** outlines initiatives to transform Europe into a global leader in innovation through a vibrant startup ecosystem.
- **Compliance Navigator (BSI)**: A digital platform to monitor regulatory compliance across 6,000+ documents.

These organizations play a critical role in helping SMEs and Startups overcome barriers to entry, scale innovation, and achieve regulatory success. Whether you are seeking funding, expert guidance, or strategic partnerships, leveraging these resources can accelerate your journey to market and strengthen your compliance.

Additional Relevant Guidance for SMEs and Startups in the MedTech Sector

For SMEs and Startups developing medical devices and in vitro diagnostics (IVDs), understanding, and applying the correct regulatory, quality, and market requirements is essential to ensure safe, compliant products reach the EU market. Below is a curated list of key regulations, standards, and guidance documents that provide foundational knowledge and strategic direction.

Core EU regulations

- **Medical Device Regulation (MDR) (EU 2017/745):** Defines requirements for placing medical devices on the EU market, covering product development, conformity assessment, certification, and post-market surveillance.
- **In Vitro Diagnostic Regulation (IVDR) (EU 2017/746):** Applies to diagnostic tests and devices, outlining approval pathways, classification rules, and performance evaluation requirements.
- **Artificial Intelligence Act (AI Act):** Establishes safety, transparency, and governance standards for AI systems, including those integrated into medical technologies.

Clinical evaluation and validation guidelines

- **MEDDEV 2.7/1 Rev 4:** EU guidance on conducting clinical evaluations for medical devices, including literature reviews and clinical data analysis.
- **ISO 14155:** International standard for clinical investigations of medical devices, ensuring ethical and regulatory compliance in study design and execution.
- **MDCG Guidance Documents** Cover clinical investigations, performance studies, and evaluation procedures under MDR and IVDR.

Product development and design

- **ISO 62366-1:** Usability engineering standard for medical devices, focusing on user safety and effectiveness.
- **ISO 13485, in relation to Design and Development Requirements:** Ensures design processes are documented, controlled, and compliant with regulatory expectations.

Risk management and safety

- **ISO 14971:** The cornerstone standard for risk management in medical devices and IVDs, covering hazard identification, risk analysis, and control measures.

Post-Market Surveillance and vigilance

- **MDCG Guidance on PMS and Vigilance** Provides frameworks for monitoring device performance, reporting incidents, and managing corrective actions post-certification.

Industry standards and best practices

- **ISO/IEC 17025:**Defines competence requirements for testing and calibration laboratories, particularly relevant for IVD manufacturers.
- **ISO 14160:** Sterilization standard for medical devices, detailing validation and testing of sterilization processes.

Guidelines for emerging technologies

- **NIBIB Guidelines** Insights into developing devices that incorporate AI, robotics, and IoT technologies.
- **MDCG Guidance on New Technologies** Addresses regulatory considerations for innovative device categories. See MDCG 2025-6 as example.

Cybersecurity and data privacy

- **ISO/IEC 27001** Information security management standard, essential for connected medical devices and systems handling sensitive health data.

Strategic insight

By familiarizing yourself with these documents and integrating their principles into your device development and compliance strategy, your organization can:

- Achieve regulatory compliance;
- Enhance product safety and quality;
- Reduce risk of non-compliance;
- Improve investor and stakeholder confidence;
- Strengthen market readiness and scalability.

Conclusion

Navigating EU regulatory compliance is a critical yet complex journey for SMEs and Startups in the MedTech sector. By adopting a structured approach, engaging early with Notified Bodies, and leveraging available guidance and support networks, organizations can streamline certification, reduce risk, and accelerate market access.

BSI's expertise, resources, and commitment to supporting innovation make it a trusted expert on the path to regulatory compliance. With careful planning, robust documentation, and strategic collaboration, SMEs and Startups can confidently bring safe, effective medical devices and IVDs to patients across Europe - driving innovation and improving healthcare outcomes.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Your partner in progress

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