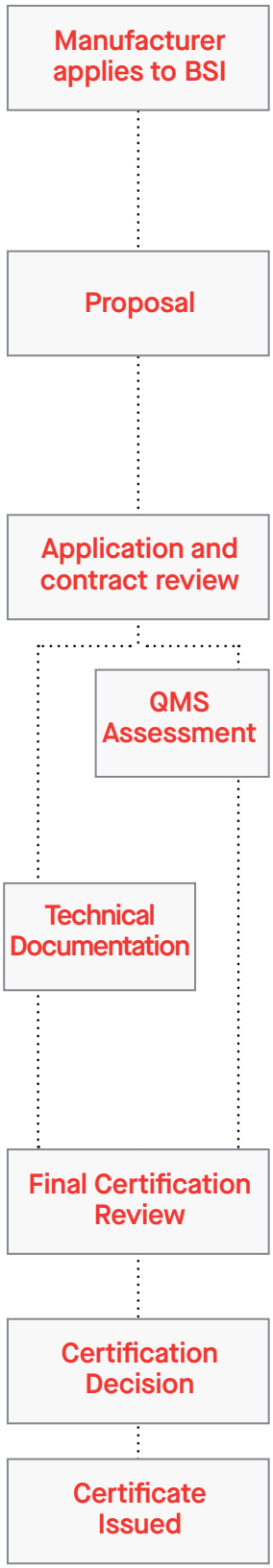
CE marking with BSI

Certification process for Medical Devices and IVD Regulations

By Royal Charter

CE Certification process

This guide will take you through our certification process starting from your application to BSI, to CE Certificate issuing to your company.



Following an initial discussion with our local commercial team, you will be given access to the pre-application process through a digital interface. This provides us with the information we need about your company and products to deliver you with an accurate proposal. Your application should include the information detailed in the appropriate Annex of the Medical Devices Regulation (MDR) or IVD Regulation (IVDR), based on your chosen conformity assessment route.

BSI will generate a proposal based on the information you submitted through the digital pre-application portal. Once accepted, the signed proposal will form the basis of the contractual agreement between your organization and BSI. On receipt of the signed proposal, BSI will assign you a dedicated team, including the Technical Specialist(s) responsible for the documentation reviews, a Scheme Manager to oversee certification activities, and a support team who will coordinate your certification. This team will remain your point of contact for all of your current and any future regulatory and certification needs.

Your Scheme Manager will review your application and resulting contract for completeness, requesting any additional information required to ensure that we assign appropriately qualified Assessors to complete your initial certification.

A specialist Quality Management System (QMS) Auditor will be assigned to assess your system to the QMS requirements of the Regulation through a two-stage assessment: Stage 1 will review the completeness of your QMS, and Stage 2 will review the effective implementation of your QMS and its compliance to the Regulation.

Note: *For devices that are sterile or end-user sterilized, additional assessment by our expert Microbiologists will be required.*

The Technical Specialist(s) with the relevant product expertise will be assigned to conduct your Product Assessment. The exact details will be based on your device classification and the appropriate conformity assessment route. Your Technical Specialist(s) will review the completeness and content of your documentation, including any additional documents or test results that provide evidence of conformity to the Regulation. They will ask rounds of questions where any gaps are identified. Your product(s) may be subject to additional assessment by specialist reviewers or consultation with a Competent Authority or the EU Commission.

Once the QMS and Product Assessments have confirmed compliance to the applicable requirements, your Scheme Manager will conduct a final review of the activities undertaken and, if satisfied that the requirements are met, will prepare a certification recommendation. They will then submit the information for final BSI Certification Decision.

All BSI certification is subject to a final internal approval process, consisting of a Technical and Regulatory Compliance check and a Quality and Internal Compliance check. This allows verification of, and consistency in, BSI certification recommendations. These final reviews are conducted by BSI staff with the appropriate technical and compliance competence.

Once approved, your certificates will be issued electronically to your organization.

Note: *As a Notified Body, BSI cannot offer consultancy advice, only auditing services.*

CE Certification: step by step

Your application

Your application for CE Certification must include the following information as per the appropriate Conformity Assessment Annex of the MDR or IVDR. This information will be reviewed as part of the QMS and Technical Documentation audits:

- Details of the legal manufacturer, including name, registered business address and the manufacturing sites covered by the QMS
- Details of the Authorised European Representative, including name and registered business address (if applicable), and details of any subcontractors
- Product details including name, classification and rationale, accessories, description, intended use and market history (if available) for device or device group covered by the QMS
- Applicable directives, regulations and standards and any test results demonstrating conformity
- Draft Declaration of Conformity for the device model covered by the scope of the certification, as per Article 19 (MDR), Article 17 (IVDR) and Annex IV
- Information of any application to another Notified Body for certification of the same device(s), including application for certification of a QMS covering this device. **If you have not applied to another Notified Body, please state this explicitly in writing**
- The QMS documentation, including the documents and procedures that describe how the manufacturer will fulfil the QMS requirements of the Regulations, and how they will apply them to maintain an effective and adequate QMS
- Evidence of conformity to the general Safety and Performance Requirements (SPRs)
- Risk management processes, including benefit-risk analysis
- Information on the design and manufacture of the devices, including product and software verification and validation processes, biocompatibility testing, stability, shelf-life and product lifetime
- The Clinical/Performance Evaluation plan and any procedures to maintain it, taking into account state of the art
- The documents detailing the manufacturer's Post-Market Surveillance (PMS) and Post-Market Clinical Follow-up (PMCF) or Post-Market Performance Follow up (PMPF) procedures (if applicable), including details on how the manufacturers will meet the requirements of the Regulations, and the procedures that maintain the PMS and PMCF or PMPF systems
- Information on how the manufacturer will meet any vigilance requirements, and explanation of how these procedures will be implemented
- User information including IFU and labelling
- Evidence of conformity to the requirements for any special processes

Your devices may be subject to additional assessment from:

- A microbiologist, a clinician
- A statistician, a toxicologist
- A medicinal product expert
- An animal/human derivative expert
- A software expert
- An EU reference laboratory
- The EU Commission
- An MRI compatibility expert
- Competent Authorities

Product Assessment

Technical Documentation review and sampling plans

The requirements for Technical Documentation review will vary based on the certificate type:

- For devices assessed under a Product Specific annex, each device will be subject to a Technical Documentation review
- For devices assessed under a Quality System-based annex, the Technical Documentation will be subject to sampling; your BSI team will request the File to be sampled

Note: *There may be some additional assessments required based on your product type and its classification, as advised by your BSI team.*

Special processes within the MDR and IVDR

The table below details the additional assessments required for some product types and/or conformity assessment routes:

Device type/Conformity Assessment Route	Additional assessments required
MDR only	
Class III implantable devices	Subject to the Clinical Evaluation Consultation Procedure, an additional assessment by the EU Commission
Class IIb active devices under rule 12	Subject to the Clinical Evaluation Consultation Procedure, an additional assessment by the EU Commission
Annex X (Type-Examination)	Notified Body to get samples of the finished devices and independently test these to recognised standards
Annex XI Part B (Product Verification)	Notified Body to examine and test individual finished devices to recognised standards
Devices incorporating a medicinal substance	Additional assessment by a BSI medicinal substance expert and consultation with a Competent Authority as per Directive 2001/83/EC is required
Devices incorporating human blood derivatives	Additional assessment by a BSI medicinal substance expert and consultation with the European Medicines Agency as per Directive 2001/83/EC is required
Devices utilizing non-viable animal tissue/cells/ derivatives	Additional assessment by a BSI animal tissue expert is required, before the co-ordinating Competent Authority gains feedback from EU Member States as per Regulation (EU) No 722/2012
Devices utilizing non-viable human derivatives	Additional assessment by a BSI human tissue expert and consultation with a human tissues and cells Competent Authority as per Directive 2004/23/EC is required
Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body (Rule 21)	For Class III devices under rule 21, additional assessment by a BSI expert and consultation with Competent Authority as per Directive 2001/83/EC is required
Devices with no intended medical purpose	BSI will only assess devices under Annex XVI if a relevant corresponding Common Specification is published. This excludes breast implants, which are regulated as Class III medical devices and some disinfectants
IVDR only	
Class D devices with Common Specification	Class D IVD devices will be assessed against the requirements of the appropriate Common Specification, and require testing at a designated EU Reference Laboratory
Companion Diagnostics	Additional assessment by the medicinal product Competent Authority or the European Medicines Agency is required
Self-tests and near patient tests	Where practicable, BSI may request an example of the device

Your supply chain

The MDR and IVDR both detail requirements for suppliers, subcontractors, Authorised Representative and other economic operators in your supply chain, including importers and distributors.

It's important to note that:

- Contracts and agreements with these parties are required as demonstration of control of your supply chain
- All critical subcontractors are required to hold valid ISO 13485 or MDSAP certification issued by an EU Notified Body or one of its direct subsidiaries. Some crucial suppliers may require appropriate certification based on the nature of the materials provided. If this is not the case, the critical subcontractor or crucial supplier may be subject to a verification audit by BSI
- BSI may carry out Unannounced Audits at the legal manufacturer locations, or their critical subcontractors and crucial suppliers

BSI resources

- **MDR Webage**
- **IVDR Webpage**
- **Whitepapers**

Additional resources

- **GHTF/IMDRF**
- **Team NB**
- **MEDDEV**
- **MDCG guidance documents**

Submission requirements

Language of Technical documentation

The official language of BSI is English; all submissions and test results should be in the English language.

Submission method

Documents should be submitted via the secure BSI Electronic Client Portal.

Documentation to be submitted

Make sure you include the Technical Documentation, the required elements of your QMS, and the signed, approved proposal when first submitting documentation to BSI. Signatures should be present where required.

Document format

The preferred document format is a paginated, bookmarked PDF utilizing Optical Character Recognition (OCR, searchable format).

Post certification activities

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

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

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