



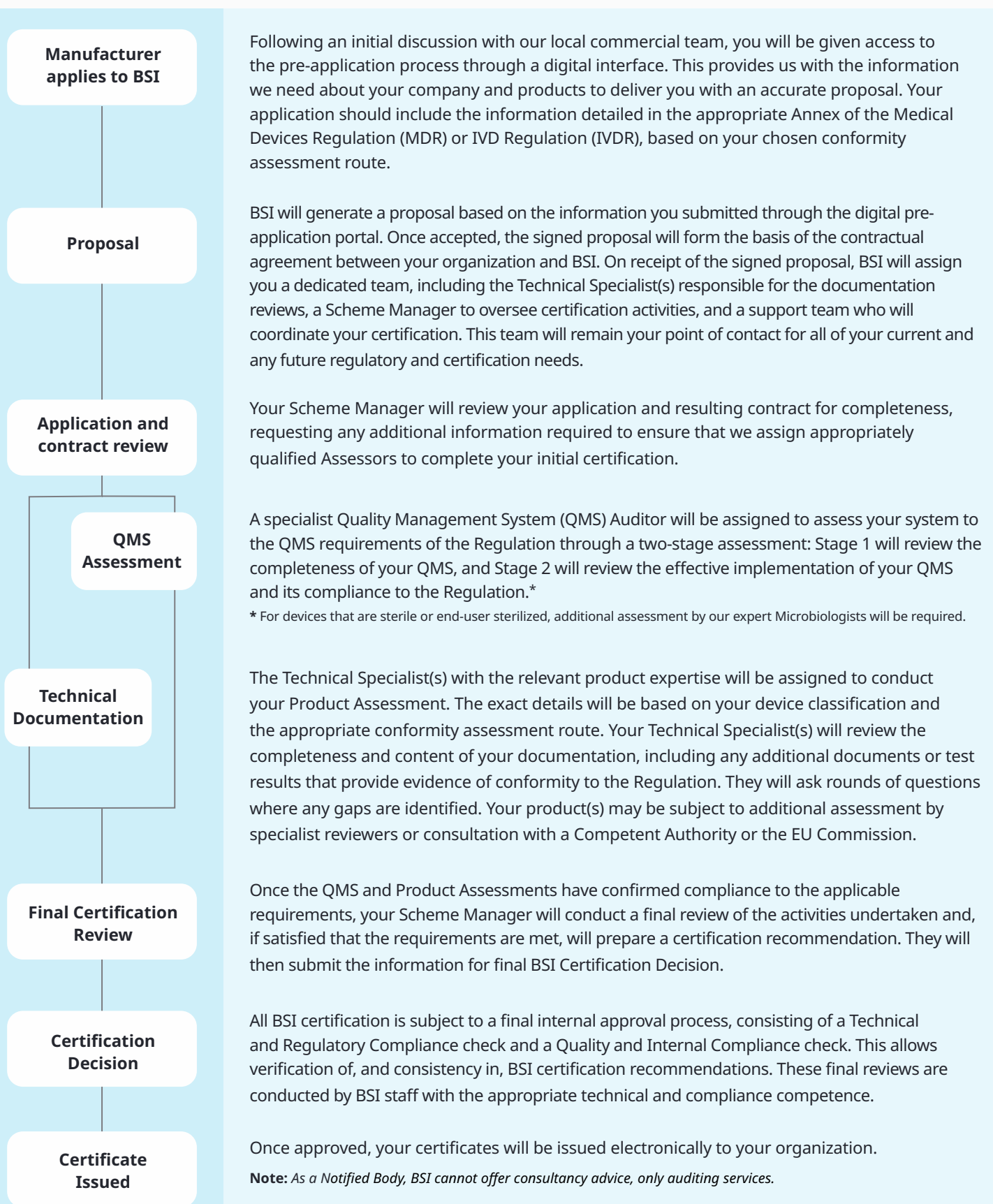
Your partner
in progress

CE marking with BSI

Certification process for
Medical Devices and IVD Regulations

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.



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 expert panel
- 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 Webpage**
- **IVDR Webpage**
- **Whitepapers**

Additional resources

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

Submission requirements

Language of Technical Documentation

All submitted Technical Documentation and test results must be in the English language. Exceptions may be allowed in the case of voluntary change of Notified Body (Transfer from another Notified Body to BSI). Please contact the BSI Account Manager or your BSI Scheme Manager for further details in case of Transfers.

Language of QMS Documentation

QMS Documentation may be in a local language. However, BSI's ability to support local languages is subject to auditor availability with the required language and technology skills and hence may have an impact on the audit planning. Additional time may be added to the audits if translation is required during the audit. Please contact the BSI Account Manager or your BSI Scheme Manager for further details.

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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