CE marking with BSI:

The certification process for the Medical Devices Regulation and IVD Regulation

This guide to our certification process will take you from your application to BSI through to a CE mark certificate being issued to your company.

Manufacturer applies to BSI

Following an initial discussion with our local commercial team, you will need to submit a Company Information Form; this gives BSI the information we need about your company and products in order to provide 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: • Annex IX section 2.1 • Annex X section 2 (MDR) • Annex XI section 6.1 (MDR) or Annex XI section 3.1 (IVDR)

Proposal

BSI will generate a proposal based on the information you include in the Company Information Form. 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.

Application and contract review

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.

QMS Assessment

A specialist Quality Management System (QMS) Assessor 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.*

Technical Documentation

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.

Final certification review

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.

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.

Certificate Issue

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

Note: *As your Certification Body, BSI cannot offer consultancy advice, only auditing services. Consultancy services are available from other independent parties.*

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CE marking with BSI: The details

Your application

Your application for CE marking 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 authorized 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 MRI compatibility expert

An EU reference laboratory

A Competent Authority

The EU Commission

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
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
Class D IVD devices	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.
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 under Directive 2003/12/EC, and some disinfectants.

Your supply chain

The MDR and IVDR both detail requirements for suppliers, subcontractors, authorized representatives 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.
- All critical subcontractors and some crucial suppliers (depending on the nature of the materials provided) will be listed in an appendix to the CE QMS certificate.
- BSI may carry out Unannounced Audits at the legal manufacturer locations, or their critical subcontractors and crucial suppliers.

Submission requirements

Language of Technical documentation.

The official language of BSI is English; all submissions and test results should be in the English language where possible. BSI may accept some parts of the Technical Documentation in another EU language if:

- The Competent Authority does not require Technical Documentation to be in a prescribed language, and
- BSI is able to allocate the Technical Specialist(s) with the correct competencies and language capabilities.

Submission method

Documents should be submitted via the secure BSI document upload 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)

For more information:

BSI resources

- BSI Guide to Notified Body
- BSI white papers, including the following titles:
  - General Safety and Performance Requirements (Annex I) in the New Medical Device Regulation
  - The European Medical Devices Regulations: What are the requirements for vigilance reporting and post-market surveillance?
  - Planning for implementation of the European Union Medical Devices Regulations – Are you prepared?
  - How to prepare for and implement the upcoming IVDR – Dos and Don'ts
  - How to prepare for and implement the upcoming MDR – Dos and Don'ts

Additional resources

- GHTF/IMDRF
- MEDDEV
- NB-MED
- NBOG Guidance

Find out more, talk to us today:

Call: **+34 91 400 86 20**
Email: **info.esp@bsigroup.com**
Visit: **bsigroup.com/productos-sanitarios**

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800,
Herndon,
VA 20170
USA

T: +1 800 862 4977/703 437 9000
F: +1 703 437 9001
E: us.medicaldevices@bsigroup.com

BSI Group - EMEA
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

T: +44 345 080 9000
F: +44 1908 814920
E: eu.medicaldevices@bsigroup.com

BSI Group Asia Pac
BSI Group - Hong Kong
23rd Floor, Cambridge House
TaiKoo Place,
979 King's Road,
Island East, Hong Kong

T: +852 3149 3320
F: +852 2743 8727
E: hk@bsigroup.com

BSI Group The Netherlands B.V.,
Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam,
The Netherlands

T: +31 20 3460780
F: +3120 346 07 81
E: info.nl@bsigroup.com