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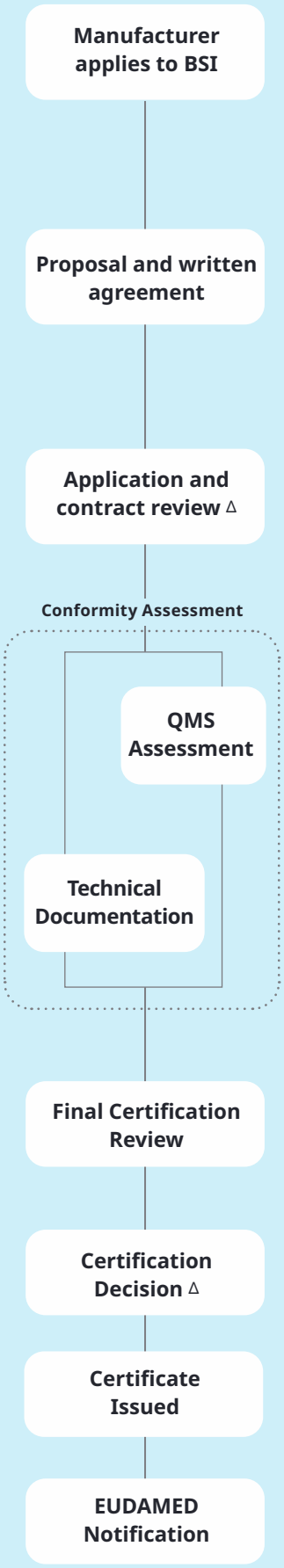
CE Certification with BSI

Certification process under 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.



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.

BSI will generate a proposal based on the information you submitted through the digital pre-application portal. The proposal will include the terms and conditions of contract. Once accepted, the signed proposal will form the basis of the contractual agreement between your organization and BSI. On receipt of the signed proposal and other application documents (as per the applicable conformity assessment route), BSI will assign you a dedicated team - a Scheme Manager to oversee certification activities, and a support team who will coordinate your conformity assessment activities. This team will remain your point of contact for all your current and future regulatory and certification needs.

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. Your Scheme Manager will review your application and resulting contract for completeness (refer to **Appendix A** for required data/documents), requesting any additional information required to ensure that we assign appropriately qualified assessors to complete your initial certification.

Our specialist Quality Management System (QMS) auditors will assess your system to 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. For devices that are sterile or end-user sterilized, additional assessment by our expert Microbiologists will be required.

Technical Specialist(s) with relevant product expertise will review the technical documentation of your devices. The exact details will be based on your device classification and the appropriate conformity assessment route. They 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 required conformity 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.

The recommendation from the Scheme Manager is subject to a legislatively mandated decision making step conducted by experienced BSI staff with appropriate competence to decide whether the legislative requirements are fulfilled and if a certificate can be issued.

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

Δ At this stage if compliance to applicable requirements is not demonstrated, the outcome will be a refusal and a refusal notification will be uploaded on **EUDAMED**.

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

CE Certification: step by step

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(s) 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

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 technical documentation of the device(s) 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 Expert Panels set up by the EU Commission.
Class IIb active devices under Rule 12	Subject to the Clinical Evaluation Consultation Procedure, an additional assessment by the Expert Panels set up by the EU Commission.
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.
IVDR only	
Class D devices with Common Specification (CS)	Class D IVD devices will be assessed against the requirements of the appropriate Common Specification, and require testing at a designated EU Reference Laboratory.
Class D without CS and first of its type	Subject to the Performance Evaluation Consultation Procedure, an additional assessment by the Expert Panels set up by the EU Commission.
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**
- **MDCG guidance documents**

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

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.
- Surveillance Technical Documentation assessments.
- Microbiology assessments, if applicable.
- Unannounced audits.
- Verification of manufactured batches (Class D IVDs).

Appendix A

List of data/documents to be submitted by the manufacturer at various phases of the process.

Data Group	Data item	Pre-application*	Formal application**
Applicant Legal Manufacturer facility (repeat for all other facilities)	Company name including legal form and website (if any)	●	
	Registered Company Number (Business Registration Number)	●	
	Street and Number	●	
	ZIP Code	●	
	City	●	
	Country	●	
	Headcount (FTEs involved in medical device(s) related activities	●	
	Applicable shifts and details of the shifts	●	
	Seasonal variations and opening and closing time		●
	Activities/processes conducted at this site	●	
	Primary contact person	●	
	SRN	●	
	Person Responsible for Regulatory Compliance (PRRC)	●	
	Identification of various economic operators like legal manufacturer, importer, supplier, distributors etc.	●	
Conformity assessment Annex	Requested conformity assessment annex(es)	●	
Authorized Representative	Company name including legal form	●	
	Street and Number	●	
	ZIP Code	●	
	City	●	
	Country	●	
	Primary contact person	●	
	SRN	●	

*Requested for the first-time during pre-application
**Requested for the first-time during formal application

Data Group	Data item	Pre-application*	Formal application**
(per) Supplier(s) (This information is usually not required for all suppliers but for suppliers having a relevant influence to the conformity of the devices, also termed as “Crucial suppliers and/or Critical subcontractors”)	Company name including legal form	●	
	Street and Number	●	
	ZIP Code	●	
	City	●	
	Country	●	
	Provided services (Functions/Activities)	●	
	Certification/accreditation information (including certificates)	●	
	Details on manufacturer’s control over supplier (this includes but is not limited to: quality agreement, supplier audits, incoming inspection, final tests)		●
Devices	Name	●	
	Variants	●	
	Part Number	●	
	Basic UDI-DI		
	Remark: in case the Basic UDI is unknown during pre-application please indicate which devices will have the same or different Basic UDI-DI	●	
	Identification as a "Medical device", "accessory", "procedure pack" or "System"	●	
	Description of device including whether it qualifies for well establish technology or not and further details on the technology including details on whether device contains any components of animal or human origin or of substances, which may be considered medicinal products	●	
	Intended Purpose	●	
	EMDN code	●	
	Classification (Include, additionally, applicable categories for class Ir devices)	●	
	Classification rules applied	●	
	Explanation / remark concerning the classification / Rationale why the device is Medical Device, if necessary	●	
	Product without intended medical purpose according to MDR Annex XVI-additional details	●	
	Re-processing details (if any)		
	Remark: please indicate if single-use devices are subject to re-processing.	●	

*Requested for the first-time during pre-application

**Requested for the first-time during formal application

Data Group	Data item	Pre-application*	Formal application**
Devices - *continued*	Identify the device as configurable device (if applicable)		●
	All facilities	●	
	Current Status of the device (e.g., covered by certificate, to be added)	●	
	Details of any novel feature	●	
	If the device contains standalone/integrated software, specify the standalone software/ firmware classification as per EN 62304. If the device incorporates Artificial Intelligence, indicate that.	●	
Sterilization processes	Sterilization method	●	
	Inhouse/outsourced	●	
	Details on the sterilization process		●
	Involved facilities	●	
	Involved suppliers	●	
Quality system Documentation	Evidence of business registration / Excerpt from the commercial register		●
	Parts of the quality management system as required by Annex IX 2.1 (or Annex XI Part A 6.1)		●
	Audit language requirements	●	
Previous Applications	Details on previous application(s) (that have not led to certification or final assessment by the Notified Body for CE) for the same device-related quality management system or devices under this application	●	
Technical documentation(s)	Technical documentation (see the remark below)		●

*Requested for the first-time during pre-application
**Requested for the first-time during formal application

Remarks:

- The data requested during one phase can also be requested again during other phase for example data requested at the pre-application phase can also be requested again during the application phase for verification or conclusion. In the table above, a particular data item is mentioned under the phase where it is requested for the first time in the process.
- The data in the table above must be kept up to date and communicated to the Notified Body at suitable intervals.
- At the time of the application, instead of the full technical documentation for each and every device, the Notified Body may find it acceptable to receive enough information about the devices to allow the notified body to verify the qualification of the products as devices, their respective classification and the chosen conformity assessment procedure including the drawing up of the conformity assessment program.

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BSI Assurance UK Ltd (0086)

Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP
United Kingdom

+44 345 080 9000

BSI Group The Netherlands B.V. (2797)

Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

BSI Group America Inc.

12950 Worldgate Drive,
Suite 800
Herndon, VA 20170
USA

+1 800 862 4977

Find our services at
bsigroup.com/medical

Email us at
medicaldevices@bsigroup.com

Find us on
LinkedIn