# UKCA marking with BSI

## Certification process for UK Regulation


**DISCLAIMER:** Contents and process of this brochure refer only to new UKCA applicants not holding any CE Certificates with BSI.

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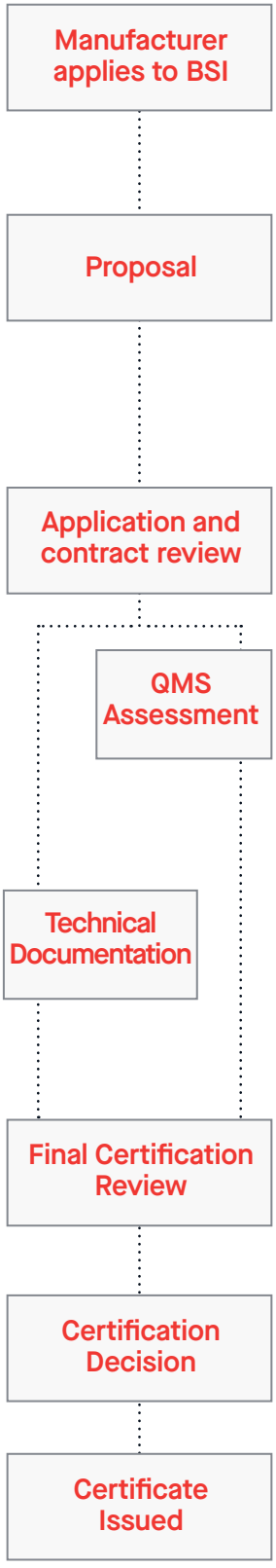
# UKCA Certification process

This guide will take you through our certification process starting from your application to BSI, to UKCA 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 UK Regulation 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 UK legislation.

**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 the MHRA.

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.

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 UK Approved Body, BSI cannot offer consultancy advice, only auditing services.*

# UKCA Certification: step by step

## Your application

Your application for UKCA Certification must include the following information as per the appropriate Conformity Assessment Annex of the UK Regulation. 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 UK Responsible Person, 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 UK legislation and standards and any test results demonstrating conformity
- Draft Declaration of Conformity for the device model covered by the scope of the certification
- Information of any application to another UK Approved 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 UK Approved 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 UK Regulation, and how they will apply them to maintain an effective and adequate QMS
- Evidence of conformity to the Essential Requirements
- 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) procedures (if applicable), including details on how the manufacturers will meet the requirements of the UK Legislation, and the procedures that maintain the PMS and PMCF 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
- The MHRA

## 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 Quality System-based annex, the Technical File will be subject to sampling. Your BSI team will request the File to be sampled
- For devices assessed under a Product Specific Annex, each device will be subject to a Design Dossier review

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

## Your supply chain

### The UK Regulation details requirements for suppliers, subcontractors, UK Responsible Person 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 UK Approved Body or one of its recognised or designated 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

- **FAQs UKCA for Medical Devices and IVDs**
- **UKCA Marking**
- **Whitepapers**

## Additional resources

- **UK Regulation**
- **MHRA website**

## 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 Approved Body (Transfer from another Approved 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 UKCA certified, BSI will continue to assess you through regular audits, including:

- QMS surveillance audits
- Technical audits for your UKCA certification
- Microbiology assessments, if applicable
- Unannounced audits

## BSI UK Approved Body (0086)

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