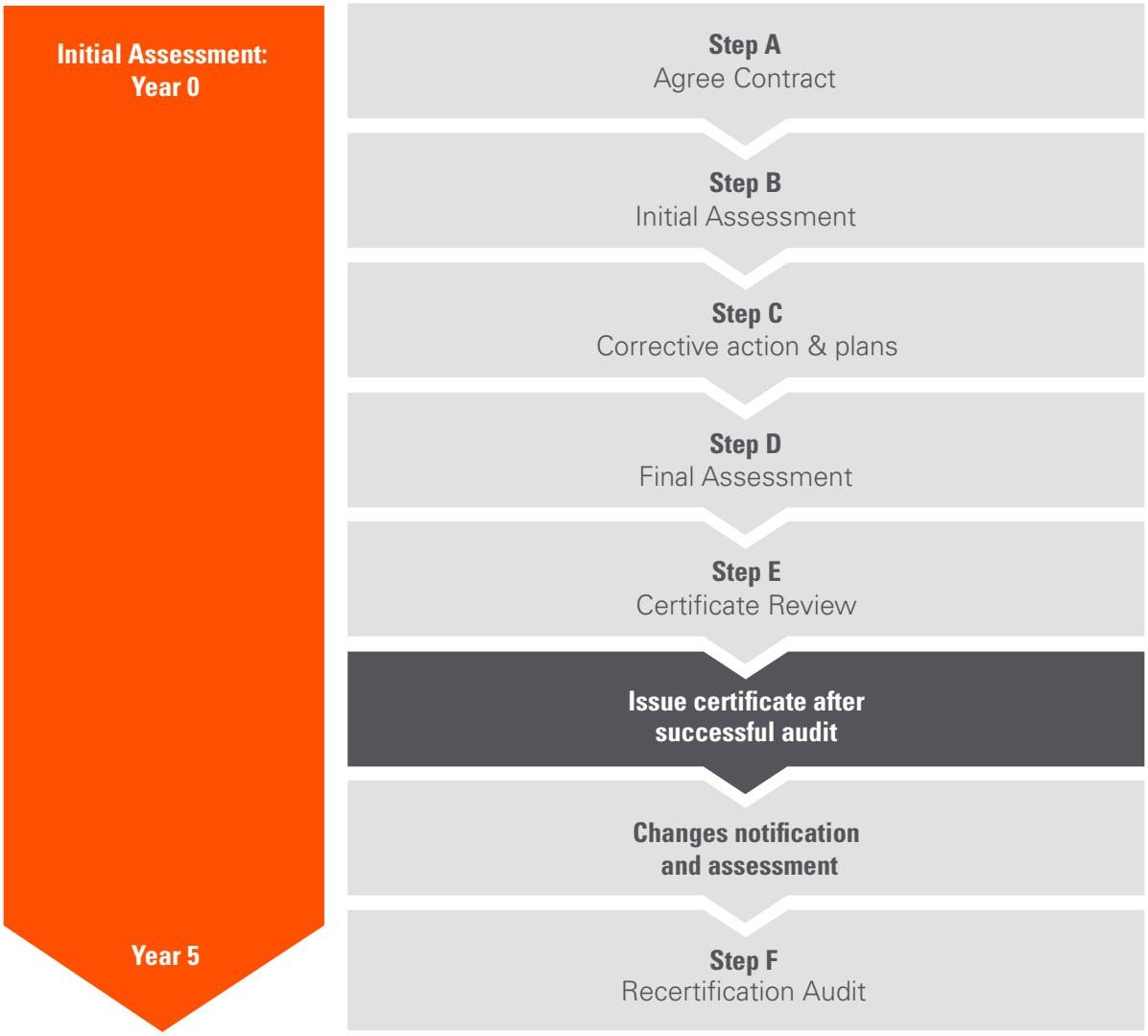
Certification Process

Part II of The Medical Devices Regulations 2002 on Medical Devices.
Annex II Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002] Design Examination

SGS

Accreditation and approval status

SGS United Kingdom Ltd is an Approved Body for this range of Class III devices and certification will be undertaken as UK Approved Body AB0120 under the UKCA Mark medical devices scheme. This means you are entitled to use UKCA Mark 0120 on devices covered by your design dossier on the completion of a successful assessment. Please note Class III devices using UKCA Mark 0120 must also be covered by a current Annex II excluding Section 4 (as modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002) certificate from SGS United Kingdom involving site audits.



Between Steps E and F, all changes must be notified to SGS using the form SGS Notification of Design Changes form (UK.MDEV.1008 form) and before implementation.

This document outlines the assessment process for the above referenced UK MDR 2002 (as amended) conformity assessment Annex. It outlines each stage of the assessment process and gives essential guidance to organizations seeking certification. It is essential that it is read and understood to minimize deficiencies and delays in certification. This document forms part of the overall information and requirements for certification services from SGS, along with the legal contract and SGS Terms & Conditions. These are defined in the Special Conditions in this document.

STEP A
PROPOSAL AND APPLICATION

A proposal is submitted by SGS for consideration. If this does not adequately include all your requirements or you have questions, please contact this office as we are happy to discuss any queries and the next steps. This proposal is valid for 60 days. Once the 60 days end, we will review the contract again and issue a new quote if necessary. SGS UK Approved Body can only issue and agree a contract with the legal manufacturer. The contract proposal is valid for a period up to 1 year maximum after acceptance. If the assessment has not been scheduled after this period, then the contract proposal becomes void and the applicant needs to re-confirm all submitted information to get a new contract proposal.

Application: To apply for certification and to start the assessment process the application form must be completed, signed and returned to this office. We recommend this is done as soon as your decision to proceed has been taken to allow maximum time for planning. Your application will be processed, and we will contact you to arrange the next steps of the audit process and dates.

What you need to send to us: Please send any application fee shown in the proposal with the application form to allow us to start the assessment process promptly.

- SGS requires a complete copy of your technical documentation (design dossier). Technical documentation should be submitted in English and electronically on CD/DVD or memory stick or file sharing downloaded sites with prior agreement. Documents should be presented in text searchable format (i.e. text recognition PDF or Microsoft Word format). All information should be appropriately indexed to allow easy access to the relevant information

- If any critical processes are subcontracted or outsourced, copies of any subcontractor current certification should also be sent

- For recertification (Step F), SGS requires, the updated technical file; sales numbers and a review of any complaints and PMS data; a list of any design changes since certificate issue; a recent or recently reviewed and revised risk analysis highlighting any new or emerging risks; any concessions or non-conformities raised since certificate issue; any change in critical subcontractors or suppliers since certificate issue; the current UK Responsible Person (if appropriate) and the current labeling and instructions for use

Special Conditions: In addition to conditions set out in the SGS Codes of Practice, General Conditions for Certification and Regulations Governing the Use of SGS Certification Marks the following apply:

Applicant (or Certified Client)

- The applicant retains full product liability for registered products or services and full responsibility for correct categorization, classification and adherence to standards

- The applicant undertakes that no other application for this scope is outstanding with another UK Approved Body. The applicant undertakes to carry out all obligations arising from a certified quality control system and maintain its adequacy and efficiency

- The applicant undertakes to inform SGS in advance of implementation of any change that could impact the compliance of the device with the UK MDR 2002 (as amended) or affect the risk benefit ratio or clinical evaluation of the device

- The applicant undertakes to institute and maintain a post-production monitoring system in accordance with the UK MDR 2002 (as amended) and any relevant national legislation and to inform SGS United Kingdom in writing of any substantiated Vigilance Reports on certificated devices

- The applicant undertakes only to affix the UKCA Mark when all requirements of UK MDR 2002 (as amended) Annex II (as modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002) are met

SGS

- SGS undertakes that no information will be disclosed to a third party, except to a regulatory or enforcement authority, where they are entitled to be informed under national legislation. This includes notification of certificate withdrawal, suspension or cancellation to other UK Approved Bodies and the UK Regulatory Authority MHRA
- SGS retains the absolute right to suspend, withdraw or amend the scope of registration by informing the organization and giving the reasons in writing. This includes suspension following a refusal to accept a scheduled or unannounced audit at your location or that of a defined critical supplier or sub-contractor or following undue restrictions or pressure during the audit
- Unless stated in the proposal it has been assumed that no audits to subcontractors or to your site are required. However, during the audit process if further information indicates a different situation, you will be informed, and visits agreed at additional cost

STEP B
INITIAL ASSESSMENT

This activity is undertaken off site. The assessment process is to determine compliance with the Essential Requirements of UK MDR 2002 (as amended) Part II Annex I, MHRA UKCA Guidelines and any relevant standards. If there are significant deficiencies, you will receive an Initial Report outlining the deficiencies (Findings). Findings must be corrected before a Final Assessment can be undertaken If this Initial Assessment results in no Findings the process moves immediately to Step D and the report you receive is a Final Report.

STEP C
CORRECTIVE ACTIONS

Findings (a common occurrence) may include documentation not included in the initial technical documentation, non-conformance to relevant standards and guidelines or weaknesses in the justification for the safety and performance of the device. These must be fully corrected before a Final Assessment can be made. After reviewing the Initial Report, you should as soon as possible contact your local contact to indicate the timescale for correction and if technical clarification is needed. When all Findings have been corrected the relevant documentation must be sent to SGS for Final Review. It is not advisable to send further documents until you have corrected all Findings. If the assessment again finds significant deficiencies, you will receive a second Initial Report indicating those Findings corrected and those which are not yet adequately corrected, and Steps B and C will be repeated at additional cost. All deficiencies must be addressed prior to a recommendation for certification; remaining residual minor issues that do not prevent certification are recorded in the form of minor TCARs and listed in the corresponding report and will need to be closed at your next surveillance audit.

For new clients or new product, if a critical finding is not closed within 1 year, then the contract will be closed and so the entire audit process must start again from the proposal stage.

For other clients or product, critical Findings have a 90 day deadline for closure, if a critical finding is unclosed after 6 months the certification will be suspended and certification withdrawn after 1 year if still open.

STEP D
FINAL ASSESSMENT

This activity is undertaken off site, although sometimes a teleconference with you may form part of this step. Again, this is to determine compliance with the Essential Requirements of UK MDR 2002 (as amended) Part II Annex I, MHRA UKCA Guidelines and any relevant standards. The assessor will agree with you the name, address and wording that will appear on your certificates and will make a recommendation for certification. You will receive a Final Report which fully describes the device, outlines your important documentation, reviews the history since original certification in the case of certificate renewals and describes any outstanding minor issues for which minor non-compliances (Corrective Action Requests) are raised. These must be corrected before the next site audit but do not delay certification.

STEP E
CERTIFICATION REVIEW

Following Final Assessment, the report is compiled and reviewed with the other audit documentation and a certification decision is made. This step can sometimes lead to limited changes in the non-conformances and scopes about which you will be informed, and your agreement obtained. Once the certification decision has been made the certificate is processed. However, certification may be restricted in scope based on the clinical evaluation of the product and requirements to conduct Post Market Clinical Follow-up (PMCF). You can use UKCA Mark 0120 as soon as you have been informed of a positive certification decision.

UK
CA
0120

Example mark

STEP F
RECERTIFICATION

Before the maximum five years validity of the certificate expires your certificate must be renewed if you are to continue to use UKCA Mark 0120. Approximately nine (9) months prior to certificate's expiry, you will receive a proposal for a recertification which should be accepted as soon as possible and sent to the UK Approved Body office. Steps A to E are then followed, although the assessment will be shorter and concentrate on changes and any new risks.

CHANGES TO SCOPE

Changes to the product design or method of manufacture or changes to critical subcontractors can be covered at any time during the certification cycle. SGS requires to be informed in advance using the SGS Notification of Design Changes form (UK.MDEV.1008 form) and should be sent to the Approved Body, so that they can be reviewed. You will receive a proposal and application form that must be signed and sent to this office. Steps A to E will then be followed.

SGS RANGE OF ADDITIONAL MEDICAL DEVICE CERTIFICATION SERVICES

For many organizations the potential market for medical devices and services is worldwide and additional certification and approvals may be required in the future. It is the policy of the SGS Group to obtain all possible global approvals to support you. Therefore, we have auditors with knowledge of a wide range of regulatory requirements:

Currently these include:

- Directive 93/42/EEC (MDD CE marking for Europe)
- JPAL – Japan Pharmaceutical Affairs Act
- MDSAP Program

USEFUL REFERENCES

- ISO 14971 Medical devices – Application of risk management to medical devices should be used in constructing your quality management system and technical documentation

- UK Regulatory Authority – Medicines and Healthcare products Regulatory Authority MHRA has UKCA medical devices scheme guidance documents available on:
  Regulating medical devices in the UK - **GOV.UK**

- The EC Commission also has documents available on their website:

  Overview | Public Health (europa.eu) which are important for classifying your devices, designing the quality management system and ensuring the correct technical documentation is available.

  Relevant guidance documents are:

  - 2.4.1 Classification
  - 2.12.1 Vigilance
  - 2.5.3 Subcontracting
  - 2.7.1 Clinical Evaluation
  - 2.7.4 Clinical Investigation
  - 2.12.2 Post Market Clinical Follow Up Studies
  - 2.14.1 Borderline and Classification
  - 2.5.1 Technical Documentation

SGS will use UKCA and other current guidance documents as relevant in the audit and assessment and should be considered as requirements.

- UK Designated Standards while not being mandatory are used by most manufacturers to demonstrate compliance with UK MDR 2002 (as amended) and so are recommended. Please check the applicable standards from the website:
  Designated standards: medical devices - **GOV.UK**

SGS United Kingdom Limited, as Approved Body 0120 has the legal address of:

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Ellesmere Port
Cheshire
CH65 3EN
United Kingdom

Canon
100
50
15
3
14
21
Sevoflurane
Isoflurane

ABOUT SGS

We are SGS – the world's leading testing, inspection and certification company. We are recognized as the global benchmark for quality and integrity. Our 96,000 employees operate a network of 2,600 offices and laboratories, working together to enable a better, safer and more interconnected world.

We offer the following main services:

- **Customized audit solutions** – our diverse skills and experiences help organizations to exploit established management systems, by working in partnership to optimize efficiency and effectiveness, finding practical solutions to challenges related to: best practices in organizational operation, process efficiency and improvement, supply chain management, and sourcing and procurement
- **Inspection services** – we inspect and check the quantity, weight and quality of traded goods. Inspection usually takes place when goods are moved from one type of transport to another
- **Testing services** – we test quality and performance of products against various health, safety and regulatory standards. We use state- of-the-art laboratories on or close to customers' premises
- **Certification services** – we confirm that systems or services meet the standards set by governments, standardization bodies (for example, ISO 9001) or our customers' products. We also develop our own standards to meet our clients' needs. SGS as an accredited certification body can provide confidence to clients that professional, experienced auditors are used and standards are consistently applied
- **Verification services** – SGS verification services ensure that products and services comply with global standards and local regulations. Combining global coverage with local knowledge, unrivaled experience and expertise in virtually every industry, SGS covers the entire supply chain from raw materials to final consumption

In the UK, SGS employs over 1,800 staff based in over 30 regional offices. Our certification section provides independent certification and audits to a range of standards, including:

- Quality Management Systems (ISO 9001)
- Environmental Management (ISO 14001)
- Risk Management, IT Certification (ISO 20000)
- Information Security Management (ISO/IEC 27001, ISO 27701, BS 10002, ISO 27017, ISO 27018)
- Business Continuity Management System (ISO 22301)
- Energy Management Systems (ISO 50001)
- Asset Management Management Systems (ISO 55001)
- Customer Service Excellence
- Occupational Health and Safety (ISO 45001)
- EC Directives (CE Mark) and other regulations
- UKCA Mark for Medical, PPE and CPR
- Medical Device Certification (ISO 13485 and MDSAP)
- British Retail Consortium Global Standards
- Food Safety Management Systems (ISO 22000)
- Aerospace

For more information on any of our services visit **www.sgs.co.uk/certification**


Review Exam
10:48:27
F# 24
0 bpm
Send to Report
Patient Directory
Send to...
Delete Selected
Undelete All
To Media as JPG/AVI
Display Exam Tree
Unselect All
Close
Page 10/12

WWW.SGS.CO.UK

WHEN YOU NEED TO BE SURE

SGS

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