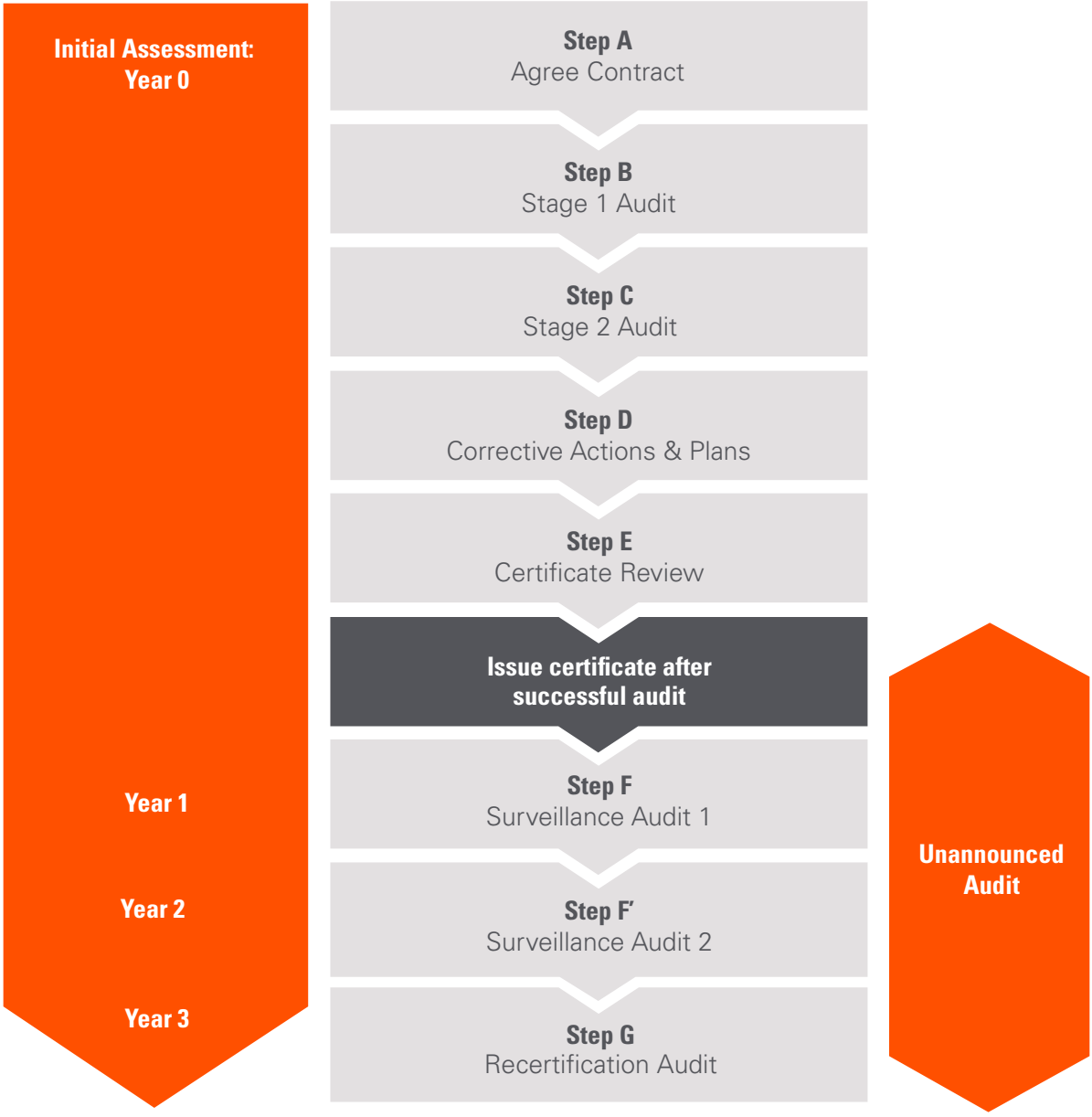
Certification Process

Part II of UK Medical Devices Regulations 2002 on Medical Devices.
Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002].
Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002].

SGS

Accreditation and approval status

SGS United Kingdom Ltd is an Approved Body for your range of products 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 within your scope on the completion of a successful audit and technical documentation assessment. Class III devices must additionally have a Design Examination certificate under Annex II section 4 (as modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002) before using UKCA Mark 0120.



Between Step F and Step G in each certification cycle additional unannounced audits will be undertaken. These will be random but will occur at least once in every three-year cycle depending on the product range and history of compliance and may be undertaken at the site of a critical subcontractor.

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 Approved Body can only issue and agree a contract with the legal manufacturer.

Application: To apply for certification and to start the assessment process the application forms 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: You do not need to make any payments on application unless payment is referenced in the proposal. To plan your audit, an SGS lead auditor will contact you to require the following information:

- A copy of your quality manual, procedures and any work instructions that ensure compliance with UK MDR 2002 (as amended) and the designated standard for quality management systems ISO 13485 (including sterilization and other critical processes). These should be controlled and sent to this office in electronic format
- To demonstrate that your internal audit and management review processes are functioning SGS needs a copy of the current internal audit schedule, the last internal audit report and the minutes of the last management review, a written declaration that no application has been lodged with any other UK Approved Body for the same device-related quality management system, or information about any previous application for the same device-related quality management system.
- A list of your sets of technical documentation (usually referred to as technical files) for the devices you wish to UKCA Mark as you may be requested to send a copy of selected technical files to this office prior to the audit
- 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 certification should also be sent
- If this is a transfer the last two audit reports from the previous certification body with any associated corrective actions should be sent

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 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 applicants needs to re-confirm all submitted information to get a new contract proposal
- The applicant undertakes that no other application to a different UK Approved Body for this scope is outstanding. The applicant undertakes to carry out all obligations arising from a certified quality control system and applicable regulations 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 send SGS copies of Vigilance Reports on certified devices. The Vigilance section below gives more details

- The applicant undertakes only to affix the UKCA Mark when all requirements of the UK MDR 2002 (as amended) are met including a valid Design Examination certificate for Class III devices

- The applicant is responsible for the all the fees and costs associated with any activity that SGS considers necessary to grant or maintain certification or which is required by the UK Regulatory Authority, MHRA. If the proposal include devices certification with technical documentation under specific additional procedure required by UK MDR 2002 (as amended) Annex II section 4 (as modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002) and external scientific opinion must be requested by the Approved Body to complete certification, associated fees not depending on the Approved Body will be invoiced additionally

- The applicant is responsible for informing SGS of all information necessary to ensure that audits, unannounced audits, assessments and communications can be efficiently and effectively undertaken, and that certification accurately reflects the current activities and product ranges and that SGS is aware of all significant proposed changes. The CHANGES section below gives more information

- The applicant is responsible for the right of access of SGS to defined suppliers and subcontractors both for the purposes of unannounced audits and scheduled audits and this must be included in your contract with critical suppliers and subcontractors. Certification of outsourced activities has not been assessed at the proposal stage, therefore if control of critical subcontractors is found to be inadequate an audit may be required at additional cost

- The applicant will facilitate as far as is legally possible the obtaining of visas for auditors to undertake audits

- The applicant takes full responsibility for the safety and security of the audit team while on site and for scheduled audits including advising on safe travel and accommodation arrangements when necessary

- As required by UK MDR 2002 (as amended) and the UK Regulatory Authority MHRA, the documentation for Class IIb implantable devices included in your scope of certification may be required for additional review by an SGS clinician following the normal assessment. This documentation will be requested in English, in electronic format and text searchable and available on a CD/USB stick or via secure download link

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 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 subcontractor or following undue restrictions or pressure during the audit

- SGS retains the right to take photographs of devices and manufacturing sites, to take samples

from the audit site and the market and to take copies of documents and electronic data

- SGS retains the right to undertake any audit, assessment or regulatory action deemed necessary to grant or maintain certification or to check compliance including visits to suppliers, subcontractors and distributors and testing of product without a further application and to charge for such work. When requested SGS will provide a written explanation for the need of any additional audit, assessment, test or regulatory action but SGS is not obliged to inform the client before such action is undertaken

- SGS will provide documentary proof of the identity of their unannounced audit team members and will provide a telephone contact point for clients to confirm the authenticity of the unannounced audit team

- Unless stated in the proposal it has been assumed that no further audits to suppliers, subcontractors or additional sites are required. However, during the audit process if further information indicates a different situation, you will be informed, and additional visits agreed at additional cost

STEP B
STAGE 1 AUDIT – PREPAREDNESS REVIEW

This activity is conducted on or off site, depending on the circumstances and your existing certification, once we have received your application. This step of the audit process includes an appraisal of your quality management system documentation and intended scope of certification, including products, processes and locations and related statutory and regulatory aspects. This stage will include:

- An evaluation of your location and site-specific conditions, and discussions with you to determine your preparedness for the Stage 2 audit

- A review of your status and understanding regarding the requirements of the standard(s) and regulations with respect to the identification of key performance or significant aspects of processes, objectives and operation of the management system

- A review to ensure that internal audits and management reviews are being planned and performed, and that the level of implementation of the management system confirms that you are ready for the Stage 2 audit

Stage 1 determines compliance with the documentation requirements of ISO 13485 and UK MDR 2002 (as amended) and the allocation of resources and working documentation for the Stage 2 audit.

You will receive a Stage 1 audit report outlining any deficiencies (findings) to enable immediate action to be taken prior to moving forward through the process. An audit plan for the on-site audit will also be forwarded to you at this stage. Serious deficiencies with the documentation, preparedness, existing certification or certification of a critical subcontractor could result in you being advised of additional costs and/or delay to the Stage 2 audit.

STEP C
STAGE 2 AUDIT – ASSESSMENT PROCESS

This step is usually conducted several weeks after the Stage 1 activity to ensure that you have time to implement the findings of the Stage 1 Audit. We are led by you in relation to the time between Stage 1 and Stage 2 activities but 4 weeks minimum would be recommended and both stages should be planned well in advance. If you need longer time, then please inform us.

This on-site audit determines compliance against your documented system, UK MDR 2002 (as amended) and relevant parts of ISO 13485. This audit will also confirm the status of critical suppliers and sub-contractors, your critical processes and the eligibility of your products for medical device certification.

All assessment conclusions are based on sampling of audit evidence to demonstrate effective implementation of the management system, control over the processes and progress made toward achieving your stated quality objectives and

compliance with UK MDR 2002 (as amended).

At the end of Stage 2 the report is compiled off site and reviewed with the other audit documentation, root cause analysis, corrective action plans and any corrective actions taken, and a certification recommendation made.

Technical documentation review: Review of Technical documentation for predetermined devices is done in parallel to the on-site audit, Stage 1 and 2. Technical documentation reviews can be undertaken on or off site. You will receive copies of any non-conformities if appropriate, and the conclusion of the reviews will be incorporated into one final report at the end of Stage 2.

Audit conclusion: On conclusion of the audit the audit team will make a recommendation dependent on the findings and subject to the submission of corrective action plans for any non-conformances (Corrective Action Requests). The auditor will talk through the findings that may comprise major and minor non-conformances. The auditor will also agree with you the name, address and proposed scope details that will appear on your certificates. The complete audit documentation will be then reviewed by the Approved Body before taking the certification decision based on the auditor's recommendation.

Audit findings: If a major non-conformance is identified, the certification decision will be deferred until corrective action has been taken and verified by the SGS auditor. Minor non-conformance will not prevent recommendation for registration but may delay it, as planned action must be submitted to and reviewed by SGS, prior to the certification decision taking place. Verification and closure of minor non-conformances will take place at the next routine surveillance visit.

STEP D
CORRECTIVE ACTIONS REQUEST AND CORRECTIVE ACTIONS PLANS

Any major non-conformance will have a corrective action plan and date agreed during the audit.

Certification will be deferred until corrective action has been taken and verified by SGS either on site or by document review as appropriate.

For new clients, if a major CAR is not closed within 1 year, then the contract will be closed and so the entire audit process must start again from proposal stage. For other clients, major CARS have a 90 day deadline for closure. If a CAR is unclosed after 6 months the certification will be suspended and certification withdrawn after 1 year if still open.

All minor non-conformances will have a corrective action plan and date agreed during the audit or immediately after and the corrective actions must be completed by the next audit. Failure to address the root cause and take effective corrective action for major non-conformances or to submit effective corrective action plans and dates for minor non-conformances will prevent final review and certification.

STEP E
CERTIFICATION REVIEW

The audit report documentation compiled by the SGS audit team will be independently reviewed by the UK Approved Body, and the final certification decision made. This step can sometimes lead to limited changes in the non-conformances and scopes about which you will be informed. Once the certification decision has been made the certificate is processed and sent to you along with the formal report.
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 & F'
ONGOING SURVEILLANCE VISITS

Once issued certificates are only valid subject to regular audits to check satisfactory maintenance of

your quality management system. Ongoing scheduled audits (surveillance visits) are conducted annually to verify continued implementation of your quality management system in accordance with planned arrangements, the requirements of the standard(s) and the requirements of the regulations. The first surveillance must be conducted within 12 months of the end of the Stage 2 audit.

Certain mandatory elements will be reviewed at every visit together with other preselected processes. You will be sent a UKCA Medical Devices Client Pre-Audit Questionnaire prior to every scheduled audit which will remind you to check on recent changes and gradual changes. It is essential that this is completed and returned to the SGS office well before the audit, but it must not be used to replace the UKCA Medical Devices Notification of Changes or Regulatory Action reporting.

An audit plan will be forwarded in advance of the agreed audit date. Please note that the flexibility in the timing of ongoing visits is strictly limited by accreditation requirements.

BETWEEN STEP F AND G ON EVERY CYCLE
UNANNOUNCED AUDITS

Unannounced audits are one of the mandatory tools used by Approved Bodies to ensure continued compliance under the UK MDR 2002 (as amended). It is therefore a legal requirement as part of the certification process against the UK Medical Device Regulations under the UKCA scheme.

These audits can be undertaken at any time within the certification cycle excluding prior agreed periods of unavailability. No notice will be given so you must always be ready to facilitate these audits.

Unannounced audits may take place at defined locations other than your site and so it is your obligation to help define these locations and to facilitate these audits. If some of the sites are not managed by you, it is your legal obligation to ensure you have contracts in place with these suppliers and/or subcontractors, which give SGS the right to make unannounced audits at their sites. These audits will concentrate on checking the production and traceability aspects of one of more recent batches of devices, witnessing the final testing and inspecting processes and auditing two processes that are critical to the safety and regulatory compliance of the devices. Samples may be taken for subsequent testing. It is a requirement that the technical documentation is available at the audit site so that it can be compared with actual or recent production.

The frequency of unannounced audits will normally be as a minimum once in every five-year period. However, this frequency may be increased for high risk devices and at the discretion of SGS if we receive information during audits or from other sources that devices may be non-conforming.

Unannounced audits to investigate any aspect of your quality management system, production processes or product compliance at any of the defined locations, in response to negative information obtained from the market or from regulatory authorities. These are referred to as "for cause" unannounced audits and may be carried out at any time.

Minimum duration of unannounced audit is 1 day for two auditors at the same time.

It is the responsibility of the client to inform SGS of all changes that are relevant to the unannounced audit including changes in the periods of unavailability and sites (please complete a Notification of Change form in this case). Charges will be made for unannounced audits that cannot be completed outside the agreed periods of unavailability.

To ensure compliance and continued certification, we request your full cooperation during the audit. The scope and nature of the audit will be further explained during the opening meeting with the SGS audit team. Please note that refusing access to your site or certain processes, or if there are significant delays, may have serious consequences such as breach of contractual obligations with SGS; other consequences may be reduction in the certified scope or even certificate suspension.

We will endeavor to cause as little disruption as is possible given the remit of our role and understand that certain key staff may be absent.

STEP G
TRIENNIAL RECERTIFICATION

SGS operates a system of continuous certification. As part of this program it is not necessary to conduct a new full Stage 1 and 2 audit rather we conduct a recertification visit which is more in-depth than a surveillance visit, and that may include an off-site document review and will ensure that we review all aspects of your quality system and technical documentation.

You will be sent a UKCA Medical Devices Client Pre-Audit Questionnaire prior to every scheduled audit that will remind you to check on recent changes and gradual changes. It is essential that this is completed and returned to the SGS office well before the audit, but it must not be used to replace the UKCA Medical Devices Notification of Changes or Regulatory Action reporting.

The recertification audit must be carried out and major non-conformances closed prior to the expiry of your current certificate. The recertification audit is the first visit of your new certification cycle.

CHANGES
REQUESTS FOR CHANGES TO YOUR SCOPE OF CERTIFICATION

In the event of any developments that will alter your scope of current certification, e.g. change of site or product range (adding or withdrawing product), reductions in scope, company name change etc., it is important you inform us as soon as possible, without any delay, as part of your change control procedure. Do not wait until a scheduled visit is being planned to notify SGS, as normally it is not possible to incorporate significant changes in a scheduled audit at short notice.

Certification does not usually extend to these changes until SGS undertakes the appropriate actions. Changes and additions to scope or significant changes in the quality management system or changes to critical subcontractors can be included at any time during the certification cycle but SGS requires to be informed in advance so that a revised contract can be issued. SGS form UKCA Medical Devices Notification of Changes or Regulatory Action is available from this office and must be used for this purpose.

Extensions can be carried out on site or off site and may or may not be added to scheduled visits. The appropriate method will be shown in the proposal.

NOTIFICATION OF OTHER CHANGES

Other changes to the operation of your company and important regulatory events also need to be notified to SGS using the UKCA Medical Devices Notification of Changes or Regulatory Action form (UK.MDEV.1007). This information is required by SGS to successfully plan scheduled audits and unannounced audits and answer queries from regulatory authorities.

Examples of changes that need to be notified are: number of employees; periods of unavailability (for client site or subcontractors); changes in shift patterns; new processes; changes to critical suppliers and manufacturing sites and adverse events reported outside the UK.

It is your responsibility to obtain from an appropriate SGS office, auditor or website the current UKCA Medical Devices Notification of Changes or Regulatory Action form and use it to notify SGS of all changes. This form contains guidance on what changes to report.

VIGILANCE
REPORTING OF VIGILANCE

It is a requirement of UK MDR 2002 (as amended) Part II medical devices and Guidance document 2.12-1 to report cases of Vigilance to your Approved Body, in this case SGS United Kingdom Limited. At the same time as reports are sent to the UK Regulatory

Authority MHRA by yourself or your UK Responsible Person, a copy must also be sent to SGS with a completed SGS form UK.MDEV.2003 *UKCA Reporting of Vigilance,* which can be obtained from your local SGS office. Documents that must be copied with a completed *UKCA Reporting of Vigilance* to SGS form are given below (note that only the applicable documents need to be supplied):

- Manufacturer's Incident Report (Initial, Final and Combined not follow-up reports)
- Manufacturer's Field Safety Corrective Action Report with attachments (e.g. copy of a Field Safety Notice) Manufacturer's Periodic Summary Report (PSR)
- Manufacturer's Trend Report

Details of the format of these documents and how to send them are included in the *UKCA Reporting of Vigilance* to SGS form.

After review by SGS we will, either file the information as input for the audit team at the next scheduled audit (in this instance there will be no communication from SGS) or inform you of actions that must be taken as soon as possible. This could include the provision of additional information to SGS, review by SGS of a technical file or information received or an unscheduled audit. Work undertaken by SGS will be invoiced.

TRANSFER OF CERTIFICATION

If you have other current certification assessed by an accredited or approved certification body and this certification is up to date and in good standing you can transfer to SGS at any time during the certification cycle. We will conduct a review of your current certification and for us to do this you will need to send us a copy of the relevant certificate(s), the previous two audit reports, including the status of any outstanding corrective actions, and the approximate due date of your next visit. Following review, we will provide you with a proposal to take over this certification within the existing cycle or starting a new cycle as preferred.

If a transfer proposal has been issued to the applicant (certified client), then it should be noted that:

- Quotation for transfer of certification is based upon the existence of current, valid and effective certification held by the applicant. Applicants must not cancel existing certification or contact their current certification body before an agreed SGS transfer date as this may invalidate the transfer process

- The transfer proposal is only valid, and the process can only proceed, if the transfer audit can be carried out at least three months in advance of the current recertification due date

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 whilst 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:

Rossmore Business Park
Ellesmere Port
Cheshire
CH65 3EN
United Kingdom

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 (ISO22301)
- 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