Your certification process explained

PART II OF 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 II SECTION 4 [As modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002] Design Examination and

ANNEX V [As modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002]

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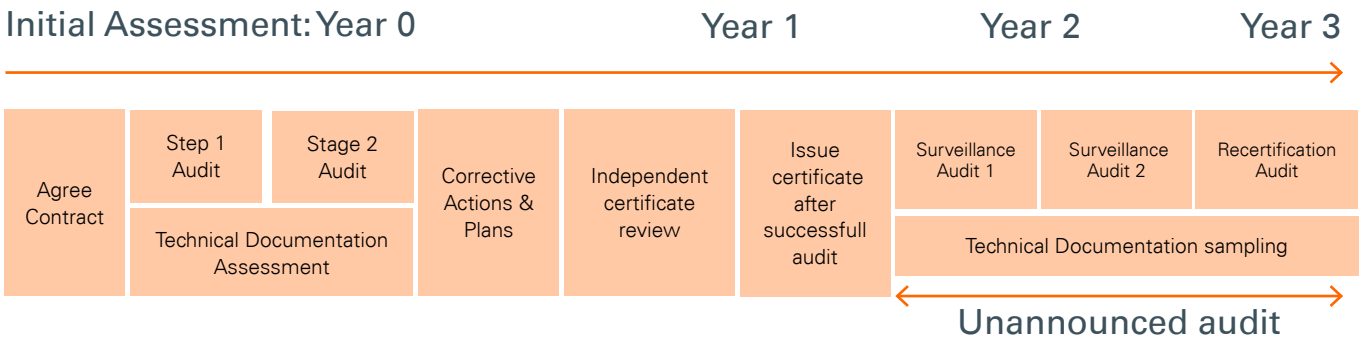
This important document outlines the assessment process for the above referenced UK MDR 2002 (as amended) conformity assessment Annexes. It outlines each stage of the audit process and gives essential guidance to organisations seeking certification and the regulatory and commercial conditions that apply. It is essential that it is read and understood to minimise non-conformities 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.

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 0120 under the UKCA Mark medical devices scheme. This means you are entitled to apply the UKCA Mark accompanied by the approved body number 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 applying the UKCA Mark 0120.

OVERVIEW OF THE CERTIFICATION PROCESS



In each certification cycle, unannounced audits will be undertaken. These will be random but will occur at least once in every three to five years depending on the product range, and history of compliance. Unannounced audits may take place at the site of a critical sub-contractor.

After the certificate has been issued all changes must be notified to SGS using the form SGS Notification of Design Changes form (GPMD1007) before implementation.

APPLICATION AND PROPOSAL

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.

SGS Proposal:

A contract proposal is submitted by SGS for your 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.

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 and form part of the contract conditions:

Applicant (or already SGS Certified Client) conditions

- The applicant retains full product liability for registered products or services and full responsibility for correct categorisation, classification and adherence to standards.
- The signed 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 applicant needs to re-confirm all submitted information to get a new Contract proposal.
- The applicant is obliged to confirm that no other application to a different UK Approved Body for this scope is outstanding.
- The applicant commits to carry out all obligations arising from the certified quality system and any applicable regulations, and to maintain the systems adequacy and efficacy.
- 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 benefit risk ratio or clinical evaluation of the device.
- The applicant undertakes to institute and maintain a post-production monitoring system for post market surveillance (PMS) in accordance with the UK MDR 2002 (as amended) and any relevant national legislation, and to send SGS copies of Vigilance Incident Reports on certified devices. The Vigilance section below gives more details.
- The applicant undertakes to affix the UKCA Mark only 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 includes device 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, any fees associated with additional external work will be invoiced in addition to the fees covered in the contract.
- 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 ensuring that SGS is granted the right of access 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 sub-contractors. 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 whilst 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 devices included in your scope of certification may be required for additional review by an SGS clinician following the normal assessment.

SGS conditions

- SGS undertake that no information will be disclosed to a third party, except to an 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 organisation 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 coercion 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, sub-contractors 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 in formed, and additional visits agreed at additional cost.

OUTLINE OF THE CERTIFICATION PROCESS

Planning the audit

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, the 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 sterilisation and other critical processes). These should be controlled and sent to this office in electronic format.
- A copy of the current internal audit schedule, the last internal audit report, and the minutes of the last management review to demonstrate that your internal audit and management review processes are functioning.
- 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 draft of your UKCA declaration of conformity in accordance with UK MDR 2002 Part II regulation 13 for the device models covered by the conformity assessment procedure.
- 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 documentation to this office prior to the audit.
- For Annex II section 4 SGS require a complete copy of your technical documentation (design dossier) for each Class III device.
- Technical documentation should be submitted in English and electronically. 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.
- For Annex II section 4 recertification audits SGS requires, the updated technical documentation; 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 copies of the current labelling and instructions for use.
- If any critical processes are subcontracted or outsourced, copies of valid subcontractor certification (where applicable) should also be sent.

- If application is for a transfer of certification from another Approved Body, then the previous cycle audit reports from your previous Certification Body / UK Approved Body with any associated agreed corrective actions should be sent.

Your application needs to be submitted in English.

We can accept that your QMS is in your local language (if accepted during proposal stage by the Approved Body) or in English.

Please note that the acceptable language for any related correspondence with UK Approved Body 0120 is English.

Stage 1 Audit

PREPAREDNESS REVIEW

This activity is conducted on-site as default but could be off-site depending on the circumstances and your existing certification. 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, 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. During Stage 1 audit the technical documentation is checked for preparedness to be sure it is up to date for technical documentation assessment.

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. Serious deficiencies with the documentation, preparedness, existing certification or certification of a critical sub-contractor could result in you being advised of additional costs and/or delay to the Stage 2 audit. An audit plan for the on-site Stage 2 audit will also be forwarded to you after this stage.

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.

The Stage 2 audit is performed on-site or as a hybrid audit (partially on-site and partially remote) and determines compliance against your documented quality 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 towards achieving your stated quality objectives and compliance with UK MDR 2002 (as amended).

Audit Conclusion: On conclusion of the audit the audit team will make a certification recommendation dependent on the findings and subject to the submission of corrective action plans for any non-conformances (Corrective Action Requests). The Lead Auditor will talk through the findings which may comprise major and minor non-conformances. The Lead Auditor will also agree with you the name, address and proposed scope details which will appear on your certificates. The audit report is compiled off site and provided to you.

Technical Documentation Assessment

The assessment of your medical device technical documentation is done in parallel to the on-site audit and is performed on a sampling basis for class IIa and class IIb. Class III and class Is devices are not subject to sampling and the technical documentation of each product is assessed.

What you need to send to us:

- A complete copy of your technical documentation. Technical documentation should be submitted in English and electronically through a secured web-based application with prior agreement from SGS (SGS secured dedicated SharePoint). 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. Please note that the acceptable language for any related correspondence with UK Approved Body 0120 is English.
- If any relevant processes are subcontracted or outsourced, copies of any subcontractor/ supplier current certification should also be sent.

Please Note: If the assessment of your technical documentation results in a high number of non-conformities, or is so poorly presented that this will be the case, then SGS may reject the technical documentation and ask you to provide a fully updated technical documentation and re-start the assessment. The review will be charged even if the review has been stopped early as the technical documentation is not compliant.

SGS UK Approved Body 0120 employs a process of Clinical Oversight to ensure adequate involvement of appropriately qualified Clinical personnel to verify compliance with the requirements of Part II of the UK MDR (general medical devices) during the assessment of manufacturers' documented Clinical Evaluation. Clinical Oversight is always applied to the assessment of Technical Documentation for Class III, Class IIb implantable devices but is only applied to Class IIa/IIb Technical Documentation assessments on a sampling basis. This process may add additional time to the conformity assessment and may result in possible changes to the non-conformances raised, modification to the scope of certification permitted or additional follow-on actions such as PMCF reviews.

For assessment under UK MDR 2002 (as amended) Part II Annex I, Regulation 722/2012 opinion from the UK Regulatory authority MHRA about Animal Tissue need to be obtained prior to UKCA marking. Only devices which can claim specific benefits from using TSE risk species will be certified. These claims and their justification must be fully documented in the technical documentation.

Corrective Action Requests (CAR) and corrective action plans

Any major non-conformance identified will have a corrective action plan and date agreed during the audit. The certification decision 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 isn't closed within 1 year, then the contract will be closed and so the entire audit process must start again from the proposal stage.

For once certification has been granted, Major CARS have a 90 day deadline for closure. If a Major CAR remains unresolved after 6 months, the certification will be suspended for a maximum of 6 months and certification will be withdrawn if the terms of the suspension are not met.

All minor non-conformances will have a corrective action plan and date agreed during the audit or immediately after. Verification and closure of minor non-conformances will normally take place at the next routine surveillance visit for QMS on-site audit and can be done on-or off-site for technical documentation assessment.

Failure to address the root cause of a non-conformance 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.

Additional time to review and close the non-conformities at a follow up assessment will be invoiced in addition to the audit or technical documentation assessment defined in the contract proposal.

Independent certification review

The audit report documentation compiled by the SGS audit team (including the corrective action plans and any corrective actions taken by you) 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.

Example

Annex II Design Examination certification for Class III devices may be restricted in scope based on the assessment of the devices clinical evaluation and requirements to conduct Post Market Clinical Follow up (PMCF). You can use the UKCA Mark as soon as you have been informed of a positive certification decision.

Annex II Section 4 [As modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002] Design Examination for Drug / Medical Device combination.

General Medical Devices that are manufactured using tissues of animal origin or their derivatives - UK MDR 2002 (as amended) Part II Annex II and Regulation 722/2012

- The Animal Tissue consultation is required under the UKCA scheme for both UKCA marked and dual UKCA/CE marked devices. SGS will consider your comments on this document before the consultation process starts. There is a specific MHRA SER form for UKCA marking, but in the interim during the transition period the MHRA will accept EU forms.
- The consultation process will take approximately 12 weeks and you will need to respond to any significant concerns expressed. If the animal material is fully supported by an EDQM certification the SER is sent to the UK Regulatory Authority (the MHRA) for information only and the 12 weeks consultation period is not required. If negative feedback is received from UK Regulatory Authority MHRA about your SER, you need to address it by further justification or documentation. If concerns cannot be adequately addressed, certification will not be issued despite the earlier preliminary recommendation of the reviewer. On the rare occurrence that SGS choose to ignore minor negative feedback and still recommend certification we must inform the UK Regulatory Authority MHRA and wait a further period for a response.

General Medical Devices that incorpoarte a medicinal substance - UK MDR 2002 (as amended) Part II Annex II and Annex I to Directive 2001/83/EC as modified by the Human Medicines Regulations 2012

- When all non-drug related Findings have been corrected and when the drug data is adequate to be reviewed, the drug related documents are sent electronically to the UK Regulatory Authority MHRA (Medicines Agency section). Where a medical device is already CE Marked and the previous consultation was with MHRA, then only a supplementary consultation is likely to be required. If the consultation for CE marking was with another EU Medicines Agency, then a full consultation will be required. Any device that has not had previous CE marking will require a full consultation with MHRA.
- All documentation for review must be written in English. This drug data must be presented in specified formats as described in the MHRA guidance documents. An additional significant fee will have to be paid at this stage, often dependent on the drug application and whether the supplier has a UK or European licence. You may wish to contact us to determine the current level of fees. This is a legally required step and may take long time depending on their workload, the adequacy of the data you have provided and the existing approval of the drug supplier. Deficiencies in the data will be passed to you from the UK Regulatory Authority MHRA (Medicines Agency) via SGS.

- Any Critical Findings from the review will have to be corrected before a positive outcome can be received from the Medicines Agency.
- Once a positive report has been received from the UK Regulatory Authority MHRA (Medicines Agency), SGS can complete their assessment.
- If negative feedback is received from UK Regulatory Authority MHRA about usefulness of a medical device incorporating an ancillary medicinal substance, you need to address it by further justification or documentation. If concerns cannot be adequately addressed, certification will not be issued despite the earlier preliminary recommendation of the reviewer.

ONGOING SURVEILLANCE AUDITS

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 after the end of the stage 2 audit.

Certain mandatory elements will be reviewed at every visit together with other pre-selected processes.

During the certification period, ongoing technical documentation reviews will also be conducted based on sampling, as defined in the SGS technical documentation matrix.

You will be sent a 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 Medical Devices Notification of Changes or Regulatory Action reporting form and regular reporting of changes.

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.

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.

Unannounced audits can be undertaken at any time within the certification cycle excluding prior agreed periods of unavailability. Any period of unavailability for you or your relevant subcontractors and suppliers need to be notified to your local SGS office for the upcoming year and not later than the end of each calendar year using the Unannounced Audit Questionnaire. In the absence of this questionnaire, SGS will consider that there is no period of unavailability. No notice will be given of unannounced audits 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.

Unannounced audits will focus 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 which 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. Minimum duration of unannounced audit is 1 day for 2 auditors at the same time.

SGS may also perform an Unannounced Audit 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.

Please note: Refusing access to your site or certain processes, or to a relevant subcontractor or if there are significant delays, may have serious consequences such as breach of contractual obligations with SGS. This may result in reduction in the certified scope or even certificate suspension. Charges will be made for unannounced audits that cannot be completed outside the agreed periods of unavailability, or if you have failed to notify us of these periods.

TRIENNIAL RECERTIFICATION

SGS operates a system of continuous certification. As part of this programme 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 which 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 Medical Devices Client Pre-Audit Questionnaire prior to the recertification 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 Medical Devices Notification of Changes or Regulatory Action reporting form.

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.

For ANNEX II SECTION 4 certificates - 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. The assessment will be shorter and concentrate on changes and any new risks

SIGNIFICANT CHANGES

Requests for changes to your scope of certification

You must inform SGS of any planned significant changes to your quality management system, or the device range covered by SGS certification by submitting a Medical Devices Notification of Changes or Regulatory Action form (GPMD1007). 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 and in advance of the change implementation. 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 require to be informed in advance so that a revised contract can be issued. The SGS form Medical Devices Notification of Changes or Regulatory Action is available from your local SGS office and must be used for this purpose. The UK Approved Body assesses the changes proposed, determines the need for additional on-site audit or technical documentation assessment and will notify the manufacturer of its decision.

An extension to scope audit can take place at the same time as surveillance/recertification visits or can be carried out between visits depending on the nature and timing of the change. This can be carried out by an on-site audit or in some cases, it is carried out by an off-site technical documentation assessment. The appropriate method will be shown in the approved change form and the proposal.

Planned significant changes are not allowed to be implemented prior to the conclusions of the change assessment by the UK Approved Body, and where applicable, conclusions of additional audits or reviewed by the UK Approved Body.

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 Medical Devices Notification of Changes or Regulatory Action form (GPMD1007) 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 subcontractors or suppliers and manufacturing sites and adverse events reported outside the UK.

For Annex II section 4 certificates changes to the product design or method of manufacture or changes to critical subcontractors can be covered at any time during the cycle. SGS require to be informed in advance using the Medical Devices Notification of Changes or Regulatory Action form (GPMD1007) and this should be sent to the Approved Body, so that they can be reviewed. You will receive a proposal and application form which must be signed and sent to this office. A contract will be issued and once signed an assessment will take place.

It is your responsibility to obtain from an appropriate SGS office, auditor or website the current 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 the UK MDR 2002 for manufacturers to report cases of Vigilance incidents 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 by email to medicaldevices.vigilance@sgs.com. This email should include information on the SGS certificates that are applicable to the device (all pertinent UKCA and CE certificate numbers) and the device classification.

Documents that must be provided to SGS 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) this can be either the output of the MHRA MORE database report, or (preferably for joint UKCA and CE products) the MIR template described in MEDDEV 2.12-1 that allows for xml data extraction.
- Manufacturer's Field Safety Corrective Action Report with attachments (e.g. copy of a Field Safety Notice).
- Manufacturer's Periodic Summary Report (PSR) when permitted.
- Manufacturer's Trend Report.

Details of the format of these documents and how to send them are included in the Medical Device Reporting of Vigilance guidance which can be obtained from your SGS local office or by emailing medicaldevices.vigilance@sgs.com.

After review by SGS we will, either file the information as input for the audit team at the next scheduled audit 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 documentation or information received, or an additional onsite audit. Work undertaken by SGS will be invoiced.

GENERAL INFORMATION

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 organisations 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:

- ISO 13485
- EU Regulation 2017/745 (CE marking for Europe)
- 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 (www.gov.uk)
- The EU Commission also has documents available on their website applicable for EU MDD that are still relevant for UK MDR 2002: Directives - European Commission (europa.eu)

  Relevant Guidance Documents are:

  - MEDDEV 2.4/1 Classification
  - MEDDEV 2.12-1 Vigilance
  - MEDDEV 2.5/3 Subcontracting
  - MEDDEV 2.7/1 Clinical Evaluation
  - MEDDEV 2.7/4 Clinical Investigation
  - MEDDEV 2.12/2 Post Market Clinical Follow Up Studies
  - MEDDEV 2.14/1 Borderline and Classification
  - NB-MED 2.5.1 Technical Documentation

SGS will use UKCA and other current Guidance Documents (where 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 (www.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

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 99,500 employees, SGS operates a network of over 2,500 offices and laboratories around the world. We offer the following main services:

- **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, standardisation 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, unrivalled experience and expertise in virtually every industry, SGS covers the entire supply chain from raw materials to final consumption.
- **Training services** - We offer over 50 different training solutions in a variety of management systems complemented by a wide range of other specialized courses. These are offered publicly, via e-learning or can be delivered in-house to suit your needs.

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 14000);
- Risk Management, IT Certification (ISO 20000);
- Information Security Management (ISO/IEC 27001, ISO/IEC 27701, BS 10002, ISO/IEC 27017, ISO/IEC 27018);
- Business Continuity Management System (ISO 22301);
- Energy Management Systems (ISO 50001);
- Customer Service Excellence;
- Occupational Health and Safety (ISO 45001);
- EU Medical Device Regulations (CE Mark) and other regulations;
- UKCA Mark for Medical, PPE and CPR;
- Medical Device Certification (ISO 13485 and MDSAP);
- British Retail Consortium Global Standard;
- Food Safety Management Systems (ISO 22000);
- Aerospace;

For more information on any of our services visit www.sgs.com.

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