YOUR CERTIFICATION PROCESS EXPLAINED

MEDICAL DEVICE REGULATION (EU) 2017/745
ANNEX IX, X AND XI

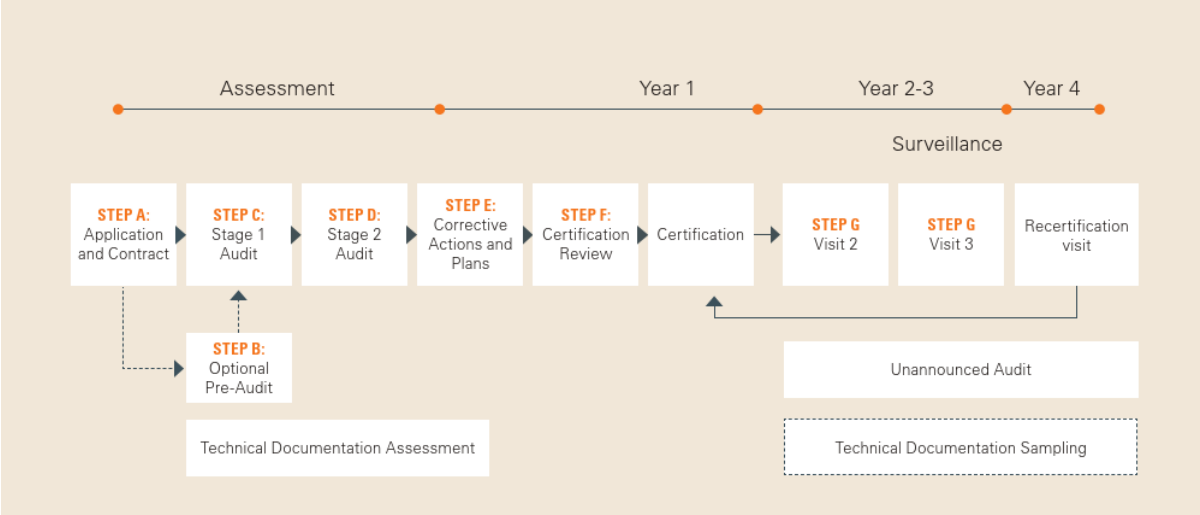
This important document outlines the audit process for the above referenced regulation. It outlines each stage of the audit process and gives essential guidance to organisations seeking certification and the regulatory and commercial conditions that apply. It is essential that it is read and understood to minimise non- conformities and delays in certification.

SGS DESIGNATION AND APPROVAL STATUS

SGS Fimko Ltd (further in the document written as SGS) is a Notified Body for your range of products and certification will be undertaken as Notified Body 0598. This means you are entitled to use CE 0598 on devices within your scope after the successful conformity assessment.

SGS Fimko's scope and applicable conformity assessment routes (Annexes) are published in the NANDO database.

OVERVIEW OF OUR CERTIFICATION PROCESS



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

STEP A

PROPOSAL AND APPLICATION

We will need a filled in MD Questionnaire (for company information) and a MD sampling plan (for list of devices to be certified with applicable risk classes and MDR codes / EMDN Codes) from you for our initial non-binding estimate of the certification costs. Supplied with our estimate are the MDR application documents.

If you are satisfied with our initial estimate, we will need your commitment to the application process. Because the application review is a demanding task, requiring multiple persons and taking at least one working day, we will invoice an application fee from you before we start the review.

In the application review we ensure that the application material is complete, the device(s) to be certified is (are) classified correctly, the selected conformity assessment route(s) is (are) applicable and that SGS is competent and able to certify the devices. Based on the application review we can prepare a detailed offer for certification and proceed to signing of the certification agreement.

The offer is valid for 30 days. Once the 30 days end, we will review the offer again and issue a new one if necessary. Please note that SGS Notified Body can issue an agreement with the legal manufacturer only.

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 information is required for application:

- Please refer to MDR (EU) 2017/745 Annex IX to XI for required documentation, depending on the selected conformity assessment route(s). Typically, these include a copy of your quality manual, procedures and any work instructions that ensure compliance with Medical Device Regulation (EU) 2017/745, appropriate common specifications and the harmonised standard for quality management systems (including sterilisation and other critical processes). These should be controlled and sent to the assessment team 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 list of your sets of technical documentation for the devices you wish to CE mark as you may be requested to send a copy of selected technical documentation to this office prior to the audit,

- Technical documentation should be submitted electronically on CD/DVD or memory stick, or SGS can arrange a protected file sharing download site 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. Acceptable languages of the documents are English, Finnish and Swedish.
  To help you in reviewing if the technical documentation covers all requirements SGS has provided to you Technical Documentation (TD) Checklist, General Safety and Performance Requirements (GSPR) and Clinical Evaluation Report (CER) Checklists. For software related products also the Cybersecurity Checklist may be applicable. The checklists include some guidance on interpretation of the requirements and in the use of checklists.
  Please complete the checklists and supply them together with the technical

documentation.
Please note that the Technical Documentation must be available for all devices that you have submitted to be certified. We will plan the sampling of the Technical Documentation according to guidance of MDCG 2019-13 and may assess only a part of the Technical Documentation at the initial certification. As the minimum we will require you to submit the completed checklists for all of the devices to be certified.

- If any critical processes are subcontracted or outsourced, copies of any subcontractor certificates should also be sent. Please note that outsourcing a process does not provide a justification for excluding it from your QMS and you must maintain control over all relevant processes.
- A written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system.

Special Conditions: In addition to conditions set out in the SGS Codes of Practice, SGS 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 categorisation, classification and adherence to standards.

The applicant undertakes that no other application to a different notified body for this scope is outstanding. The circumstances of any previous Notified Body application will be documented by the applicant and sent to SGS before an application is accepted.

The applicant undertakes to carry out all obligations arising from a certified quality management system and applicable regulations and maintain its adequacy and efficiency.

The application is valid for a period up to 1 year maximum after acceptance. If the assessment has not been scheduled after this period, then the application becomes void and applicant needs to re-confirm all submitted information to get a new Contract proposal. If the manufacturer is not able to provide sufficient evidence of corrections and corrective actions of any major QMS audit nonconformity within 6 months after the last day of stage 2, we must conduct another stage 2 prior to recommending certification. For Technical Documentation nonconformities it is possible to extend the deadline up to maximum of 12 months. If the certification decision cannot be made within 18 months from the end of Stage 2 audit, the certification must be refused. The refusal will be reported according to Medical device regulation (EU) 2017/745. To continue the certification process, the manufacturer must submit a new certification application.

The applicant understands that the termination of an ongoing certification process by the applicant before its completion will be handled as a refusal to certify and will be reported accordingly.

The applicant undertakes to inform SGS in advance of implementation, of any change that could impact the compliance of the device with the Medical device regulation (EU) 2017/745 or affect the risk to benefit ratio or clinical evaluation of the device.

The applicant undertakes to institute and maintain a post-production monitoring system in accordance with Medical Device Regulation and any relevant national legislation and to send SGS copies of any Vigilance Reports on certified devices. The VIGILANCE section below gives more details.

The applicant undertakes only to affix the CE Mark when all requirements of the Medical Device Regulation (EU) 2017/745 are met, including a valid Technical Documentation Assessment certificate for Class III and specific IIb 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 a European Competent Authority.

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 sub-contractors.

The applicant is responsible that all importers of the device and all distributors of the device are aware of and fulfilling their obligations as defined in the Medical device regulation (EU) 2017/745.

If the applicant does not have a registered place of business in a EU Member state, the applicant is responsible to have valid agreement with an authorised representative (EU REP) before certification takes place. In the application phase a draft mandate for the designation of an EU REP and a letter of intention from the EU REP to a accept the mandate are adequate.

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 for advising on safe travel and accommodation arrangements when necessary.

SGS

SGS undertake 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 Medical device regulation (EU) 2017/745. This excludes information publicly available in EUDAMED according to Medical device regulation (EU) 2017/745 as this cannot be considered as confidential.

SGS retains the absolute right to refuse to certify the quality system or the device in a case where the applicant is not able to provide documentation or records required to provide evidence for compliance in appropriate time or is not able to correct major nonconformities in appropriate time while the certification process in ongoing.

SGS retains the absolute right to suspend, withdraw or amend the scope of certification 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 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 retain 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.

When requested, 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 offer 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.

Upon request by client, an optional informal pre-audit (Step B) may be performed to clarify and confirm the scope of the application before proceeding to Stage 1 audit (Step C). The pre-audit is possible only after the certification agreement has been signed by both parties.

STEP C

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, 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 II audit.

Stage 1 determines compliance with the documentation requirements of Medical device regulation (EU) 2017/745 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 stage 2 on-site audit will also be forwarded to you at this stage. If you are requested to send SGS copies of technical documentation these will also be reviewed, and you will receive copies of any non- conformities if appropriate. The reviews will normally be incorporated into one final report at the end of Stage 2. 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.

STEP D

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.

This on-site audit determines compliance against your documented system, Medical Device Regulation (EU) 2017/745 and relevant parts of ISO 13485. Unless undertaken off site it will also include a review of selected technical documentation. 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.

If relevant, reviews of technical documentation of your products are done in parallel to the onsite audit. Notice that the review of the technical documentation usually requires several weeks and sometimes even months of calendar time to complete. The review time largely depends on the complexity, novelty, and risk class of the product being reviewed. One month should be reserved for the completion of a technical documentation review of a typical simple class IIa device.

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 Medical Device Regulation (EU) 2017/745.

At SGS our audit approach is designed to contribute value to the process and to ensure that your management system is achieving your goals.

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 which may comprise major and minor non-conformances. The auditor will also agree with you the name, address and proposed scope details which will appear on your certificates.

Complete audit documentation set will be then reviewed by the Notified Body before taking certification decision based on auditor's recommendation.

Audit Findings: If a major non-conformance is identified, the certification decision will be deferred until corrective action has been taken. 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 E

CORRECTIVE ACTIONS AND 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. If a Major CAR isn't closed in 1 year, then the contract will be closed and so the entire audit process must start again from proposal stage.

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 F

CERTIFICATION REVIEW

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 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.

The certification has a maximum validity of five years. Decision and justification for the applied validity will be made case by case.

STEP G

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 usually 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. In some cases, dependent on the scale, nature of your operations and scope of certification 6-monthly surveillance visits have been agreed at the proposal stage. Certain mandatory elements will be reviewed at every visit together with other pre-selected processes

Surveillance audits will be coupled to a sampling of devices to verify that the manufactured devices are

in conformity with the technical documentation and regulatory requirements. Sampling may include testing of material, component or product samples.

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.

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 H ON EVERY CYCLE

UNANNOUNCED AUDITS

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 to investigate product compliance may be undertaken by SGS at any defined locations other than your site and, so it is your obligation to help define these locations and to facilitate these audits.

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 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 once in at least every five-year period. However, this frequency is increased for high risk devices in every three-year period or 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.

STEP H

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 audits 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 system and technical documentation.

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.

For the Recertification you need to submit a summary of changes and scientific findings for the certified devices. More detailed information of what is required is provided in the FPMDREG2001 *Medical Devices Client Pre-Audit Questionnaire*.

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, reductions in scope, company name change etc it is important you inform us as soon as possible.

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 A SGS form *Medical Devices Notification of Changes or Regulatory Action* is available from this office and must be used for this purpose.

For definition of significant changes please refer to MDCG 2020-3. SGS reserves the right to update the definition, based on internal procedures and future MDCG guidance.

The scheduling of any extension to scope of audit can take place at the same time as a surveillance/recertification visits or can be carried out between visits depending on the nature and timing of the change. This is carried out by an on-site audit STEP D and the certification process carries on through STEPS E and F.

In some cases, extension to scope is carried out by an off-site Technical documentation assessment STEP C and will bypass STEP D. The appropriate method will be shown in the approved change form and the proposal. Notice that the review of the technical documentation of a new or a significantly changed device usually requires several weeks and sometimes even months of calendar time to complete. The review time largely depends on the complexity, novelty, and risk class of the device being reviewed and especially how the change may affect clinical evaluation. Small changes to an existing product are quicker to complete and may be completed, in simple cases, in less than two weeks.

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. 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 included are: number of employees; periods of unavailability, changes in shift patterns, new processes; changes to critical suppliers and manufacturing sites and adverse events reported outside the EU.

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 Medical Device Regulation (EU) 2017/745 to report cases of Vigilance to appropriate EC Competent Authority either on the European Electronic system on vigilance and on post market surveillance when fully functional or using the relevant form, by you or your European Authorised Representative. A copy of the report submitted to the competent authority must also be sent to SGS with a completed SGS form FPMDREG2003 *Reporting of EC Vigilance to SGS* which can be obtained from your local SGS office.

Documents that must be copied with a completed *Reporting of EC Vigilance to SGS* form include but are not restricted to the following:

- Manufacturer's Incident Report (Initial, Final and Combined follow up reports)

- Manufacturer's Field Safety Corrective Action Report with attachments (e.g. copy of a Field Safety Notice)
- Manufacturer's Periodic Safety Update Report (PSUR)
- Manufacturer's Trend Report

Details of the format of these documents and how to send them are included in the *Reporting of EC 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 documentation or information received or an unscheduled audit. Work undertaken by SGS will be invoiced

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

It is a requirement of Medical Device Regulation (EU) 2017/745 for Class IIb implantable and Class III medical device manufacturers to draft a summary of safety and clinical performance as part of its technical documentation. This summary must be validated by SGS and uploaded in the European database on medical devices (article 33, Medical device regulation (EU) 2017/745).

After review by SGS we will, either upload in the European database on medical devices (article 33, Medical device regulation (EU) 2017/745) (In this instance there will be no communication from SGS) or inform you of further requested action.

It is the responsibility of the client to maintain the SSCP documentation and keep it up to date.

PERIODIC SAFETY UPDATE REPORT

It is a requirement of Medical Device Regulation (EU) 2017/745 (article 86 of MDR) for class II and III medical device manufacturers to:

- prepare,
- update annually for IIb and class III and at least every two years for others
- upload it annually into the electronic system on vigilance and post market surveillance (article 92 of MDR) for IIb implantable and class III only,

a periodic safety update report (PSUR) as part of its post market surveillance activities. This summary must be assessed by SGS and an evaluation report by SGS must be uploaded as well in the electronic system on vigilance and post market surveillance (article 92 of MDR).

After assessment and uploading of the assessment by SGS we will or inform you of any actions that must be taken. This could include the provision of additional information to SGS, review by SGS of a technical documentation or information received or an unscheduled audit. Work undertaken by SGS will be invoiced.

Manufacturers of class I device shall prepare a post market surveillance report and update it when relevant. This report may be requested by competent authority.

GENERAL

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 a review, we will provide you with a proposal to take over this certification within the existing cycle or starting a new cycle as preferred.

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.

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.
- In addition to understanding the requirements, *Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU)* is useful in understanding the assessment process
- The EC Commission has many documents available on their website https://ec.europa.eu/health/md_sector/new_regulations/guidance_en which are essential for classifying your devices, designing the quality management system and ensuring the correct technical documentation is available.
- European Harmonised Standards whilst not being mandatory are used by most manufacturers to demonstrate compliance with Medical Device Regulation (EC) 2017/745 (MDR) and so are recommended. Please check the applicable standards from the website https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

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 90,000 employees, SGS operates a network of over 1,800 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 specialised courses. These are offered publicly, via e-learning or can be delivered in-house to suit your needs.

Our certification section provides independent certification and audits to a range of standards, including:

- Quality Management Systems (ISO 9001);
- Environmental Management (ISO 14001);
- Occupational Health and Safety (OHSAS 18001);
- EC directives (CE Mark) and other regulations;
- Medical Device Certification (ISO 13485, MDSAP and UKCA);
- Welding Quality Assurance ISO 3834;
- AQAP Quality Assurance;

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