# YOUR CERTIFICATION PROCESS EXPLAINED

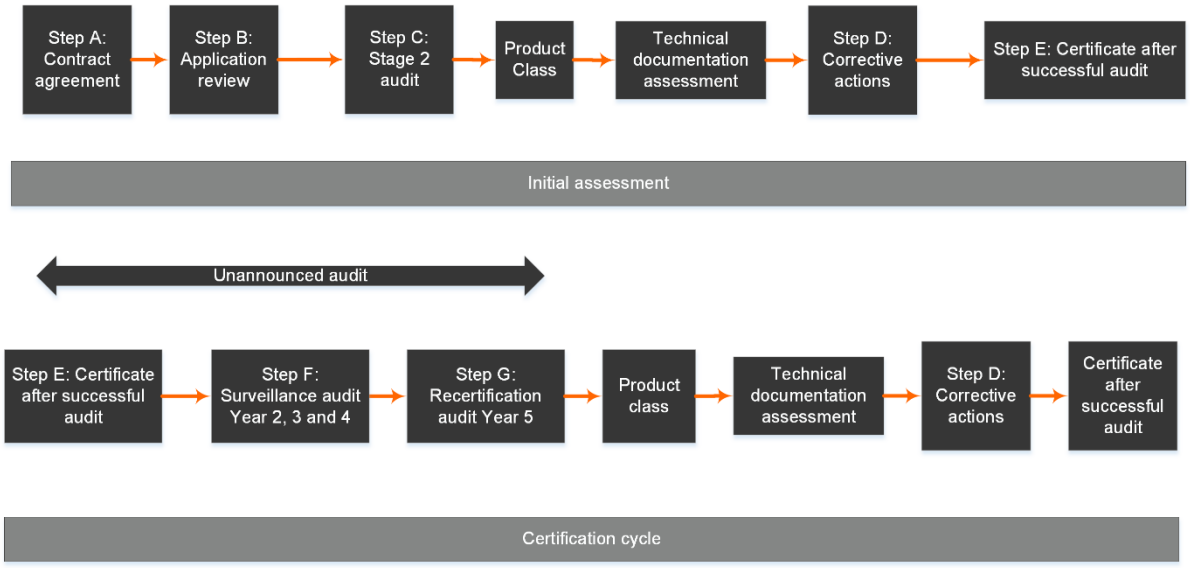
## MEDICAL DEVICE REGULATION (EU) 2017/745
## ANNEX IX AND XI PART A

**This important document outlines the audit process for the above regulation. It outlines each stage of the audit process and gives essential guidance to organizations seeking certification and the regulatory and commercial conditions that apply. It is essential that it is read and understood to minimize nonconformities and delays in certification.**

## SGS DESIGNATION AND APPROVAL STATUS

SGS Belgium NV is a Notified Body for your range of products and certification will be undertaken as Notified Body 1639. This means you are entitled to use CE 1639 on devices within your scope on the completion of a successful audit and technical documentation assessment. Class III, implantable class IIb[1] and class IIb active devices intended to administer and/or remove a medicinal product must additionally have a technical documentation assessment certificate before using CE 1639.

## 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-year cycle depending on the product range and history of compliance and may be undertaken at the site of a relevant subcontractor and/or supplier.

The certification cycle is normally based on 5 years. However, SGS may, based on documented evidence, decide to reduce the cycle in 1 or 4 years depending on the results of initial, surveillance and recertification conformity assessment as authorized by MDR (EU) 2017/745.

[1] Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.

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

**Application:** To apply for certification and to start the assessment process the contract proposal 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 assessed and 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. SGS requires the following elements:

- Completed & signed Medical Device Questionnaire that is available on our website (https://www.sgs.com/en/health-and-nutrition/health-science/solutions/medical-devices/eu-medical-devices-regulations-information-center)
- Completed & signed Product Information Questionnaire(s) that is available on our website(https://www.sgs.com/en/health-and-nutrition/health-science/solutions/medical-devices/eu-medical-devices-regulations-information-center): preferable one per technical documentation to be certified but minimal one per device for class III and specific[2] class IIb devices, one per generic device group for class IIb and one per device category for class IIa and specific [3]I devices)
- a draft of an EU declaration of conformity in accordance with MDR 2017/745 Article 19 and Annex IV for the device model covered by the conformity assessment procedure
- the documentation on the manufacturer's quality management system
- a documented description of the procedures in place to fulfill the obligations arising from the quality management system and required under MDR and the undertaking by the manufacturer in question to apply those procedures
- a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures
- the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in MDR 2017/745 Articles 87 to 92
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in MDR 2017/745 Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures
- documentation on the clinical evaluation plan
- a description of the procedures in place to keep up to date the clinical evaluation plan, considering the state-of-the-art
- 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 harmonized standard for quality management systems

[2] class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and class IIb active devices intended to administer and/or remove a medicinal product.

[3] class I devices placed on the market in sterile condition, have a measuring function or are reusable surgical instruments

(including sterilization and other critical processes). These should be controlled and sent to the assessment team in electronic format

- all elements listed in MDR 2017/745 Section 2.1 of Annex IX
- a copy of the EU type-examination certificates referred to in MDR 2017/745 Section 4 of Annex X if relevant and issued by another Notified Body than SGS Belgium NV if you need a certificate Annex XI section A
- 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
- When requested, technical documentation, as well as any further evidence in response to corrective action requests, should be submitted in English and electronically on a secured USB stick or alternatives or by electronically secured web-based application with prior agreement from SGS (preferable SGS secured server Share Files). 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 and follow the requirements of MDR Annex II and Annex III
- 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 Notified Body) or in English
- If any critical processes are subcontracted or outsourced, copies of any relevant subcontractor/supplier certification should also 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 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 control system and applicable regulations and maintain its adequacy and efficiency.

The application is valid for a period of up to 1 year maximum after the effective date of the contract. If the assessment has not been scheduled after this period, then the contract proposal becomes void and the applicant needs to re-confirm all submitted information to get a new Contract proposal.

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-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 devices, implantable class IIb[4] and class IIb active devices intended to administer and/or

[4] Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.

remove a medicinal product.

The applicant is responsible for 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. If the Proposal includes devices certification with technical documentation under specific additional procedure required by MDR (EU) 2017/745 section 5 and external scientific opinion have to be requested by the Notified Body to complete certification, associated fees not depending on the Notified 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 each of its sites covered by the certification scope including defined suppliers and subcontractors, both for unannounced audits and scheduled audits (initial, surveillance and recertification). This must be included in your contract with relevant suppliers and subcontractors. Therefore, the applicant must communicate annually the period during which unannounced audits can't be conducted for each of its relevant suppliers and/or subcontractors.

Certification and control of outsourced activities has not been assessed at the Contract proposal stage, therefore if certification and control of relevant subcontractors and relevant suppliers are found to be inadequate after application, an additional 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.

**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 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 confidential.

Competent authorities including EU experts and the Joint assessment team may access all information gathered during assessment of the applicant to verify that that conformity assessment has been conducted by SGS in accordance with MDR requirements.

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 relevant 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 for 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 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

### APPLICATION REVIEW AND STAGE 1 AUDIT – PREPAREDNESS REVIEW

An application review & stage 1 is conducted on- or off-site once we have received your application. During this step, the Notified Body will:

- review the completeness of the application with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex in MDR, under which approval has been sought,
- review the verification of the qualification of products covered by the application as devices and their respective classifications,
- review whether the conformity assessment procedures chosen are applicable to the device in question under MDR
- reconfirm that the devices and the conformity assessment procedures chosen are within the designation of the Notified Body SGS.
- reconfirm the availability of sufficient and appropriate Notified Body assessment resources for timely performing all tasks.

The outcome of the review of the application may be (exceptionally) a refusal of the application (e.g. if incomplete applications, non-conformities or problems in the application documents are detected).

The application review /stage 1 is conducted on-site as default but could be off-site if specific circumstances are met. Application review 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:

- Review of all documents and elements listed in Annex IX section 2.1
- 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. Technical Documentation (which is mandatory part of the application) will also be reviewed, where applicable, on a sampling basis, and you will receive an assessment report including non-conformities if appropriate. The reviews will normally be incorporated into one final report at the end of Stage 2. Serious deficiencies with the QMS and technical documentation, preparedness, existing certification or certification of a relevant subcontractor and/or supplier could result in you being advised of additional costs and/or delay to the Stage 2 audit QMS audit or initial technical review of the technical documentation.

## STEP C

### STAGE 2 AUDIT – ASSESSMENT PROCESS

This step is usually conducted several weeks after the Stage 1 – Application review 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. This audit will also confirm the status of relevant suppliers and subcontractors, your critical processes and the eligibility of your products for medical device certification.

Technical documentation of your product will be done on a sampling basis for class IIa and IIb excluding implantable class IIb[5] and class IIb active devices intended to administer and/or remove a medicinal product. For class IIa devices the sampling plan is based on device subcategory. The appropriate code from Implementing Regulation 2017/2185– MDA or MDN will be used to determine a representative sample. Devices that are under the same MDA or MDN code are in the same category. For class IIb devices (excluding those which require a technical documentation examination under Annex IX, sections 4 and 5), the sampling plan is required to be based on the generic device group defined based on EMDN code level 4 for MDR. The 4th level of the EMDN nomenclature in respect of the MDR (i.e. combination of one letter plus 6 digits) competed by level 2 and 3 level of ENMD when there is no level 4 available.

For implantable class IIb[6] and class IIb active devices intended to administer and/or remove a medicinal product as well as for class III, technical documentation of each product are assessed.

The assessment of the (sampled) medical device technical documentation is done in parallel to the on-site audit.

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 the 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 a 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. 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 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.

For new clients, 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. For other clients, Major CARS have a 30-day deadline, which may be extended if there is justification and at SGS discretion, if unclosed at 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

[5] Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.

[6] Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.

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

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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. You must be informed that Certificate validity may be reduced to between 1 to 5 years during the certification decision process based on multiple aspects that would be justified to you if relevant.

## STEP 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) must be 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 assessment of the (sampled) medical device technical documentation is done in parallel to the on-site audit.

The first surveillance must be conducted within 12 months of the end of the stage 2 audit all subsequent surveillance audits must then be completed within 12 months of the previous audit. Certain mandatory elements (including device testing and technical documentation review based on sampling) will be reviewed at every visit together with other pre-selected processes 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.

During surveillance audit, one or more devices should be tested (witnessing test) according to the defined sampling plan but if this can't be achieved on-site, devices will be sampled and tested outside of the manufacturer's site and the cost will be invoiced in addition to the audit cost.

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 E AND G ON EVERY CYCLE

### UNANNOUNCED AUDITS

These audits can be undertaken at any time within the certification cycle excluding prior agreed periods of unavailability. Unannounced audit cycle is associated with your certificate, so if you have multiple conformity assessment procedures leading to multiple certificates you will have one unannounced audit cycle per certificate. Your period of unavailability and the ones from your relevant subcontractors and suppliers will be asked once a year per SGS using the Unannounced audit questionnaire. In the absence of feedback to this questionnaire, in the month following the request by SGS, SGS will consider that there is no period 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 the 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 once in 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 an 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 program, it is not necessary to conduct a new full Application review/Stage 1 and Stage 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.

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

You shall inform SGS of any plan for substantial changes to the quality management system, or the device-range covered, substantial changes are described in MDCG 2020-3 *Guidance on significant changes regarding the transitional provision under article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.*

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 and in advance of the change implementation.

Certification does not usually extend to these changes until SGS undertakes the appropriate actions. Changes and additions to the scope or significant changes in the quality management system or changes to relevant subcontractors and/or suppliers 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. An SGS form *Medical Devices Notification of Changes or Regulatory Action* is available from this office and must be used for this purpose.

The Notified Body SGS Belgium shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements referred to in Section 2.2 of Annex IX of MDR. SGS Belgium shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device range covered shall take the form of a supplement to the EU quality management system certificate.

Planned changes are not allowed to be implemented prior to the conclusions of the assessment by the Notified Body SGS Belgium, and where applicable, conclusions of additional audits or reviewed by the Notified Body.

The scheduling of any extension to the scope of 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 is carried out by an on-site audit STEP D and the certification process carries on through STEPS E and F. In some cases, it 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.

### 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 in advance of the change implementation. 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: number of employees; periods of unavailability (including relevant subcontractors and relevant suppliers); changes in shift patterns; new processes; changes to relevant subcontractors and/or 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 post-market surveillance when fully functional or using the Manufacturer Incident Report (MIR) for Serious Incident (MDR/IVDR) and incidents (AIMDD/MDD/IVDD) – Reporting template version 7.2, 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 LPMD(REG)2003 Reporting on 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 are one of the following:

- 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 *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 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 implantable devices[7], 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

[7] Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling.

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.

## PERIODIC SAFETY UPDATE REPORT

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

- prepare the periodic safety update report (PSUR) as part of its post-market surveillance activities
- update at least annually for class IIb, class III devices and at least every two years for class IIa devices
- upload it annually into the electronic system on vigilance and post-market surveillance (article 92 of MDR) for IIb implantable and class III only
- make PSURs available to the Notified Body involved in the conformity assessment and, upon request, to competent authorities for devices other than class III devices or implantable devices

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 file or information received or an unscheduled audit. Work undertaken by SGS will be invoiced.

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

## GENERAL

### TRANSFER OF CERTIFICATION

If you have other current MDR certifications assessed by a designated Notified 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), audit reports from the previous cycle, 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 start a new cycle as preferred.

### 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:

- 3P510k
- MDSAP Program
- UKCA

## 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.
- The EU Commission has many documents available on their website (https://ec.europa.eu/health/md_sector/new_regulations/guidance_en):
  - Common Specifications are provided by the Medical Device Coordination group and represent a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system
  - Guidance's (MDCG guidance)
- European Harmonised Standards whilst not being mandatory are used by most manufacturers to demonstrate compliance with Medical Device Regulation (EU) 2017/745 (MDR) and so are recommended. Please check the applicable standards from the website https://ec.europa.eu/health/md_topics-interest/overview_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 **95,000 employees**. SGS operates a network of over **2,400 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 the 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.
- 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.

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

- Quality Management Systems (ISO 9001);
- Environmental Management (ISO 14001, BS8555 and EMAS);
- Information Security Management (ISO 27001);
- Public Sector Customer Service Excellence;
- Occupational Health and Safety (ISO45001);
- Corporate Responsibility (SRA);
- EC directives (CE Mark) and other regulations;
- Medical Device Certification (ISO 13485 and MDSAP);
- Food Safety Management Systems (ISO 22000).

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