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**Document Title:** LPMD1014 - Proposal Annex BE ISO13485

**Document Notes:**

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## LPMD1014 - Proposal Annex BE ISO134

### Technical Approval

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Bart Mersseman (BART_MERSSEMAN) | | 14 Apr 2017, 01:51:30 AM | Approved |

### QHSE Approval

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Pieter Weterings (PIETER_WETERINGS) | | 14 Apr 2017, 07:46:40 AM | Approved |

### Quick Approval

### Approve Now

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| System Administrator (SYSADMIN) | | 10 Dec 2019, 05:27:26 PM | Approved |

### Quick Approval

### Approve Now

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| System Administrator (SYSADMIN) | | 12 Dec 2019, 10:22:42 AM | Approved |

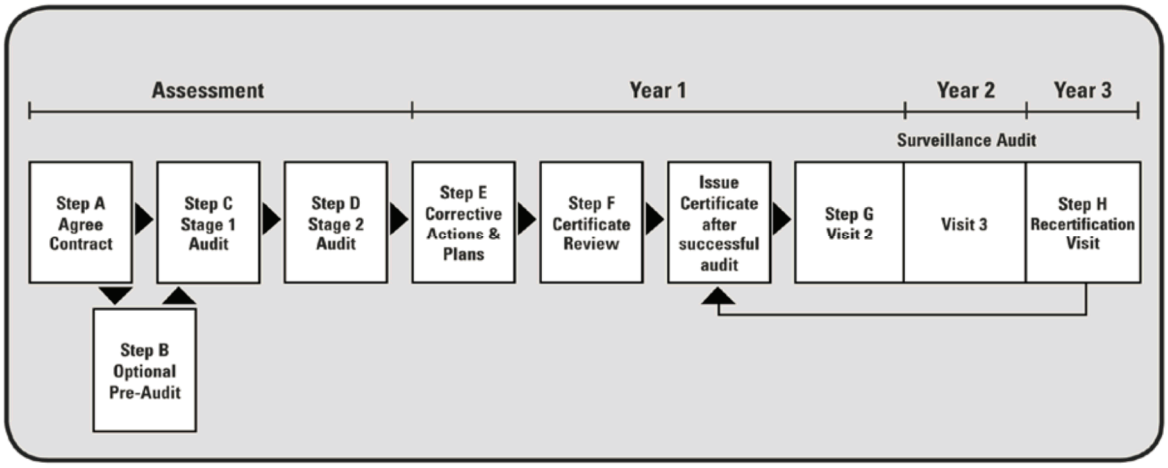
# YOUR CERTIFICATION PROCESS EXPLAINED

## ISO 13485:2016 BELAC
## MEDICAL DEVICES – QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS FOR REGULATORY PURPOSES

This document outlines the audit process for the above referenced standard(s). It outlines each stage of the audit process and gives essential guidance to organizations seeking certification.

## ACCREDITATION AND APPROVAL STATUS

SGS Belgium NV is BELAC accredited for quality management systems including ISO 13485:2016 for all medical devices and associated services. This means you are entitled to use both the SGS and BELAC logos on the completion of a successful audit.







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## 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 3 months. Once the 3 months end, we will review the contract again and issue a new quote if necessary.

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

**What you need to send to us:** You do not need to make any payments on application unless a payment is referenced in the proposal. Unless a pre-audit is being undertaken, SGS require a copy of your quality manual, procedures and any work instructions that ensure compliance with ISO 13485:2016 (including sterilisation and other critical processes). These should be controlled and sent to this office in paper or electronic format. You should indicate for paper copies whether it is an original to be returned or whether it is to be eventually destroyed by SGS (our normal procedure). To demonstrate that your internal audit and management review processes are functioning SGS need a copy of the current internal audit schedule, the last internal audit report and the minutes of the last management review. If any critical processes are subcontracted or outsourced, copies of any subcontractor certification should also be sent. If this is a transfer the last two audit reports from the previous certification body with any associated corrective actions should be sent.

**Special Conditions:** In addition to conditions set out in the SGS Codes of Practice, General Conditions for Certification and Regulations Governing the Use of SGS Certification Marks the following apply: The applicant retains full product liability for registered products or services and full responsibility for correct categorisation, classification and adherence to standards. Unless stated in the proposal it has been assumed that no audits to 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

### PRE-AUDIT (AT YOUR REQUEST)

This activity is designed to ensure you are ready for the audit and certification process, that you have considered all the requirements of the standards and regulations and to minimise subsequent delays through non-compliances. This service cannot be offered by SGS as this is considered consultancy. It is forbidden by current regulations for Notified Bodies to offer any form of consultancy.

However, a stage 1 audit is a fully acceptable activity done conducted the Notified Body to review the preparedness for certification as explained below (STEP C). Such audit can be undertaken in an early stage of the certification process and when requested by the company or considered required by the auditor as a result of the audit, be repeated after detected shortcomings are corrected and gabs are eliminated.





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## 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 II audit;
- a review of your status and understanding regarding the requirements of the standard(s) and regulations, in particular 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 the standard(s) and regulations and the allocation of resources and working documentation for the Stage II audit. You will receive a Stage I audit report outlining any deficiencies (findings) to enable immediate action to be taken prior to moving forward through the process. An audit plan for the on-site audit will also be forwarded to you at this stage. Serious deficiencies with the documentation, preparedness, existing certification or certification of a critical sub-contractor could result in you being advised of additional costs and/or delay to the Stage II audit.

## STEP D

### STAGE 2 AUDIT

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, the standard(s) and the appropriate regulations.

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.

At SGS our audit approach is designed to contribute value to the process and also 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 non-conformances, minor non-conformances and observations/opportunities for improvement. The auditor will also agree with you the name, address and scope details which will appear on your certificates.





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## 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 raised, a major non-conformance needs to be closed as soon as possible and the corrective action taken need to be verified and accepted by SGS within 3 months after the major non-conformance is raised. Late review of the corrective action taken may lead to a deferred certification or suspension of the (existing) certificate until the review is finished and found acceptable.

All minor non-conformances will have a corrective action plan and date agreed during the audit or immediately after and the corrective action must be completed by the next audit. Failure to 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, 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, and your agreement obtained.

Once the certification decision has been made the certificate is processed and sent to you along with the formal report and guidance on the use of the SGS and BELAC logos. SGS can support you in the form of certificate presentations and arranging press releases to help you promote your achievement should this be required.

If the certification decision cannot be made within a reasonable time (maximal 12 months) after the first assessment task by the Notified Body (stage 1 or review of technical/clinical documentation) due to a delay in the project or major non-conformities (in the quality management system or technical/clinical documentation), the certification process will be aborted and a new application will be required. However, the new application may take into account the work already done.

## 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 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 II audit. In some cases, dependent on the scale, nature of your operations and scope of certification six-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. We will work with you to identify areas that are not conforming to support opportunities for improvement. 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.

If raised, a major non-conformance need to be closed as soon as possible and the corrective action taken need to be verified and accepted by SGS within 3 months after the major non-conformance is





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raised. Late review of the corrective action taken may lead to suspension of the certificate until the review is finished and found acceptable.

## STEP H

### TRIENNIAL RECERTIFICATION

SGS operates a system of continuous certification. As part of this programme it is not necessary to conduct a complete reassessment. Rather we conduct a recertification visit which is more in-depth than a surveillance visits and which may include an off-site document review and will ensure that we review all aspects of your system. 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.

## GENERAL

### PAYMENT TERMS

We will send you an invoice for the fees when we have carried out each stage. Once you receive an invoice, you must pay it within 30 days after the date of invoice (no matter what your company's payment terms) unless we agree otherwise in writing.

If you require a purchase order it is your responsibility to ensure this is supplied to SGS, either prior to the date of audit on the booking confirmation letter or given to the auditor during the on-site visit.

### CHANGES TO SCOPE

In the event of any developments that will alter your certification, e.g. site or scope additions, reductions, mergers or acquisitions, it is important you inform us at your earliest convenience. Changes to scope or significant changes in the quality management system or changes to critical subcontractors can be covered at any time during the certification cycle. SGS require to be informed in advance so that a revised contract can be issued and an SGS form Notification of Proposed Major Changes to the Quality System is available for this purpose and should be sent to this office. The scheduling of any change to scope of audit can take place at the same time as a surveillance/renewal visit or can be carried out between visits depending on your requirements and instructions. Usually this is carried out by an on-site audit STEP C and the certification process carries on through STEPS D and E. In some cases, it is carried out by a document review STEP B and will bypass STEP C. The appropriate method will be shown in section 2.1 of the proposal.

### SWITCH 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 switch to SGS at any time during the certification cycle. We will conduct a review of your current certification and in order 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





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## 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 and we can help your future plans by offering:

- Training
- Direct additional regulatory certification
- Additional regulatory certification via other SGS affiliates

*Currently these include*:

- Directive 93/42/EEC (MDD CE marking for Europe)
- Directive 98/79/EC (IVD CE marking for Europe)
- FDA 21CFR Part 820 (USA)
- Canadian Medical Devices Regulations and CMDCAS ISO 13485: 2003 (Canada)
- Therapeutic Goods Regulations and TGA ISO 13485:2003 (Australia)
- Pharmaceutical Affairs Act and ISO 13454:2003 (ROC Taiwan)
- Pharmaceutical Affairs Law (JPAL) and #169 (Japan)
- Hong Kong Medical Device Regulations

## GUIDANCE AND ADVICE TO CLIENTS SEEKING CERTIFICATION

1. As the title of ISO 13485:2016 is Medical devices – Quality management systems – Requirements for regulatory purposes, the medical device regulatory requirements under which you sell products are considered requirements of your quality management system and should be included where relevant.
2. ISO 13485:2016 also references ISO 14971:2007 Medical devices – Application of risk management to medical devices and this standard needs to be addressed within your quality management system.





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## ABOUT SGS

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 80,000 employees, SGS operates a network of over 1,500 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 9000) 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.





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