# Regulations for Certification of Quality Assurance and Quality Management Systems of SLG Prüf- und Zertifizierungs GmbH

## 1 Scope

These Regulations for Certification apply for the assessment and certification of quality assurance and quality management systems (hereinafter referred to as “QA / QM systems”) conducted by SLG Prüf- und Zertifizierungs GmbH (hereinafter referred to as “SLG”) for clients on the basis of valid laws and standards. If applicable, accreditation and / or notification regulations are to be observed additionally.

## 2 Object

2.1 Prior to confirmation of an order, all information necessary for the certification process shall be compiled, usually by questionnaire.

2.2 The certification process comprises the following individual services based on established procedures:

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|---|---|
| a) Application review | Review of client information and decision on accepting or rejecting the application |
| b) Stage 1 Audit: | Is undertaken at initial certification in order to determine whether the organisation is ready for certification |
| c) Stage 2 Audit: | Undertaking the certification audit |
| d) Certification decision | Issuing the certificate if all requirements are met |
| e) Monitoring: | Annual monitoring during the term of the certificate |
| f) Re-Certification: | Undertaking a re-certification audit before the certificate expires after an application was filed |

2.3 The actual scope of services shall be agreed by a contract between SLG and the client prior to the application review.

## 3 Commitments of SLG

3.1 SLG is an independent provider of services. SLG provides services equally to all clients without discrimination or delay.

3.2 The assessment and certification of the client’s QA / QM system is based on the German Product Safety Act (ProdSG), the German Medical Devices Act (MPG), DIN EN ISO 9001, DIN EN ISO 13485 and other relevant standards and directives, depending on the assignment. Assessments and certifications are conducted by qualified auditors in accordance with the procedures established at SLG and verified by independent bodies.

3.3 Prior to the audit, SLG discloses the names of and, if requested, background information on each member of the audit team. The client is thus given the opportunity to object to the appointment of a particular auditor or technical expert; otherwise the client confirms with their signature on the audit plan that they approve of the audit team. In case of a well-founded objection the certification department shall arrange for a new audit team.

3.4 The tasks of the audit team are defined as below. The audit team shall:

a) examine and verify the structure, policies, processes, procedures, records and related documents of the client organisation relevant to the management system (QM / QA system),

b) determine that these meet all the requirements relevant to the intended scope of certification,

c) determine that the processes and procedures are established, implemented and maintained effectively in order to provide a basis for confidence in the client's management system (QM / QA system) and

d) for the client's own measures, communicate to the client any inconsistencies between the client's policies, objectives and targets (consistent with the expectations in the relevant management system standard or other normative document) and the results.

3.5 In case the QA / QM system complies with all relevant requirements – documented in an audit report or in a final report of a QA assessment – SLG grants certification and issues a certificate provided that all conditions are met.

3.6 During the validity period of the awarded certificate annual monitoring audits are conducted. Furthermore, SLG is authorised to conduct audits announced at short notice or no notice at all within the scope of certificate monitoring and in justified cases. According to the Medical Device Directive 93/42/EEC, unannounced visits to the certificate holder shall be conducted in order to monitor whether their quality management system is working properly (please see also 5.11).

3.7 In order to maintain the certification after the certificate has expired, a re-certification including a re-certification audit conducted within the period of validity of the original certificate is required.
However, a potential re-certification is not being undertaken automatically and shall be arranged in a separate agreement between the client and SLG.

3.8 Refusal of certification by SLG shall be accompanied by justification in writing. SLG shall not be liable for any disadvantages the client may experience as a result of the refusal. Any new application submitted by the client later than six months after the refusal of the certification shall require a re-assessment based on a separate order.

3.9 The client is aware that SLG is awarded specific authorisations by higher bodies which SLG might be deprived of. Should such a case occur, SLG will inform the client immediately. Otherwise the existence of authorisations applies as basis of a contract about certification services between SLG and the client. In case of frustration of contract SLG is not obliged to conduct any further certification services. SLG will support the client during transition to a new accredited / notified body. As far as a frustration of contract is concerned, the client shall not be entitled to any claims against SLG.

3.10 SLG reserves the right to terminate the contractual agreement on which the certification services are based for good cause if the fulfilment of the contractual services cannot be ensured due to reasons of changed requirements and / or necessary resources. The client shall not be entitled to any claims against SLG due to a termination based on the above mentioned reasons.

3.11 SLG is obliged to treat all information and business secrets revealed to them by the client as strictly confidential and not to use them for any other than the purpose contractually agreed upon. The obligation to confidentiality shall remain in force following the termination of the contract.

3.12 The client is, however, aware that SLG is obliged to disclose any refused, revoked, withdrawn, restricted, suspended and misused certificates to authorised bodies (e.g. authorities, monitoring bodies, accreditation bodies, steering committee etc.) and to provide access to documents available at SLG to third parties and / or to release such documents (including copied) to them. Disclosure of information and releasing documents to such authorised bodies shall not be regarded as a breach of the confidentiality obligation.

3.13 According to DIN EN ISO/IEC 17021-1, SLG shall provide information – if requested – about:

a) Geographical areas in which SLG operates

b) The status of a given certification

c) The name, related normative document, scope and geographical location (city and country) for a specific certified client

In exceptional cases, access to certain information can be limited on the request of the client (e.g. for security reasons).

3.14 SLG retains all internal and external order documents during processing and after completion in accordance with the corresponding legal provisions and relevant regulations.

3.15 SLG is obliged to directly inform the client / certificate holder about essential regulatory changes of the relevant certification process for the certificate holder.

## 4 Validity of Certificates

4.1 The certificate awarded by SLG contains all essential information concerning validity, certificate holder, location as well as the client's scope of business, of activities and of products.

4.2 The certificate becomes void on expiration of the stated validity and shall not be used by the client afterwards. The client may apply for a re-certification according to paragraph 3.7 within the period of validity of the original certificate.

4.3 A certificate may be refused, revoked, restricted or withdrawn if the requirements for issuing or maintaining the certificate are not met or not met anymore or have not been met at any time and if

a) the client misuses certificates and approval marks of SLG or of the accreditation body or a notification authority,

b) deviations or deficiencies in the QA / QM system are found during monitoring or re-certification audits, where compliance of the products or of parts of the certification scope with the essential requirements of the relevant directives and standards can no longer be guaranteed,

c) the client refuses monitoring actions,

d) the client fails to pay fees in due time which were agreed upon in the contractual agreement and SLG's fee scale,

e) withdrawal of the certificate is legitimately demanded by authorities or other higher bodies.

4.4 In any case, the certificate holder shall be informed and heard prior to any intended change of the certificate status (according to paragraph 4.3, among others). For certifications in the field of medical devices, § 18 MPG shall apply.

4.5 Enquiries about the validity of certificates may be made via SLG's website.

## 5 Commitments of the Client

5.1 The client commits towards SLG in particular to:

a) support SLG in any monitoring actions taken to ensure compliance with the certification rules and requirements,

b) submit all essential documents and procedure documents to the auditors appointed by SLG. All documents submitted remain with SLG. Documents of which copies are made by SLG will be charged to the client.

c) support SLG in conducting regular audits on the basis of the agreed audit plan and to grant access to all locations, equipment, materials and products required by the audit scope,

Note: In addition to the physical visit of the facilities, “on-site” may also include, if required, remote access to electronic site(s), which contain(s) information relevant for the audit of the management system.

d) ensure the availability of personnel, as required by the audit plan, to be interviewed during the audit as well as the availability of one authorised client representative for regulations, coordination and information.

Note: If not otherwise agreed to by the audit team leader and the client, each auditor shall be accompanied by a guide. The guide(s) is (are) assigned to the audit team to facilitate the audit. If required, the guide is responsible for:

- establishing contacts and scheduling interviews;
- arranging visits to specific parts of the site or organisation;
- ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;
- witnessing the audit on behalf of the client;
- providing clarification and information as requested by an auditor.

5.2 The client is obliged to fulfil all legally required assurances concerning the QA system, in particular:

a) to obligations arising from the approved QA system,

b) to keep the approved QA system adequate and effective,

c) to introduce and keep up to date a systematic procedure for reviewing experience gained from products in the post-production phase and to implement appropriate measures for taking corrective action as well as to inform the relevant authorities and SLG immediately – in accordance with current laws and regulations – on any incidents arising.

5.3 The use of the QM system test mark in relation to any product advertising (e.g. statements concerning the product’s quality on the type plate or packaging, etc.) is not permitted.

5.4 The client shall inform SLG about changes

a) of the legal, economic or organisational status or ownership,

b) within the organisation or the management (e.g. key managing personnel, decision makers or experts),

c) of the client’s contact address and locations,

d) of the scope and product range registered for certification,

e) which are essential to the management system and processes.

Any change may require an assessment by SLG. In any case, the client shall ensure that legal regulations and essential requirements to the QA / QM system are fulfilled.

5.5 SLG conducts annual monitoring audits at the client's site(s). The client shall pay all costs arising thereof to SLG according to the contractual agreement.

5.6 The client shall record any customer complaints and inform SLG thereof.

5.7 The client shall inform SLG immediately about any recalls, incidents, near incidents and measures taken.

5.8 The client of a certification service covered by legal provisions declares that they have not filed any application with any other certification or notified body for assessment / certification of their QA / QM system.

5.9 The client facilitates Observed / Witness Audits by higher bodies or the participation of SLG's auditors in training at the production facilities of the manufacturer and their subcontractors.

5.10 Document checks and audit reports as well as protocols shall be forwarded only in their full wording stating the date of issue. A publication in part shall require SLG's prior written approval. The documents remain the property of SLG.

5.11 In order to ensure a targeted execution of unannounced audits in the framework of procedures according to Medical Device Direction 93/42/EEC, Annexes II, V and VI, the client is obliged to inform SLG about periods of production inactivity. This obligation is valid during the whole duration of the certificate awarded.

## 6 Rights of the Client

6.1 During the validity of the certificate the client shall be entitled to refer in their legal relations to the awarded certificate and entitlement to use test marks derived thereof, always provided that they observe the legal regulations and other relevant standards and directives (in particular DIN EN ISO 9001, DIN EN ISO 13485). Furthermore, the client shall observe the regulations of the SLG Mark Statute.

6.2 On the basis of an additional agreement, the client shall be entitled to use the SLG company logo in connection with the certification.

6.3 The client has the right to file complaints or appeals with SLG, particularly concerning SLG's decisions and regulations. SLG comments on the complaint or the appeal and informs the client. In case no agreement can be reached, SLG shall consult other entities. Detailed information about processing complaints is defined in the document "SLG Complaints Procedure" and may be sent to the client on request.

## 7 Infringements of these Regulations for Certification of QA/ QM systems

In case of infringements of these Regulations or of the SLG Mark Statute by the certificate holder, in particular in case of illegal use or misuse of SLG certificates and / or marks, SLG is entitled to take corresponding measures, which may result in restriction, suspension or withdrawal of the SLG certificate and the entitlement to use test marks derived thereof.

## 8 Validity

8.1 These Regulations shall become effective on the date stated in the footer below.

8.2 Changes of legal provisions, accreditation or notification regulations as well as the generally acknowledged rules of technology, relevant standards and directives shall be met by both parties, SLG and the client without prejudice to these Regulations for Certification. In case any of these afore mentioned changes occur, SLG shall adapt the Regulations for Certification regularly and continuously. SLG shall inform the client about those changes.