SLG Prüf- und Zertifizierungs GmbH

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

Content:

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1. Scope

These Regulations for Certification applies for the evaluation and certification of quality assurance and quality management systems (hereinafter: QA/QM systems) conducted by SLG Prüf- und Zertifizierungs GmbH (hereinafter: SLG) for clients.

2. General

(1) The general procedure for a certification process can be found in the associated information, which is publicly available on the website “www.slg.de.com”.

(2) The exact scope of services and thus the requested certification procedure must be agreed contractually between SLG and the client.

(3) SLG is an independent service provider. SLG provides its services equally and without discrimination to all clients.

(4) The client has the right to file complaints and 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”, published on SLG’s website and may be sent to the client on request.

(5) The client is aware that SLG as an Accredited and Notified Body is authorised to issue certificates within the scope of the accreditation or notification. This does not mean that the Accredited Body or Notified Body is responsible for the result of the certification.

(6) In case of infringements of these Regulations 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 certificate and the entitlement of rights of use as well as using test marks derived thereof.

3. Commitments of the SLG

(1) Depending on the assignment, the evaluation and certification of the client's QA/QM system is based on DIN EN ISO 9001, DIN EN ISO 13485, the Medical Device Regulation (EU) 2017/745 (hereinafter: MDR) and other relevant standards and directives. These activities are conducted by qualified personnel in accordance with the procedures established and approved by SLG.

(2) Prior to the audit, SLG discloses the names of and, if requested, qualifications and current activities of 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 by signing the audit plan that the client approves the audit team. In case of a well-founded objection about competence or impartiality, the certification department shall arrange a new audit team.

(3) In case the QA/QM system complies with the requirements – documented in an audit report or a final assessment report – and all requirements are met, certification is granted and a certificate will be issued.

(4) During the validity period of the awarded certificate, surveillance audits are conducted at least once a year. Within the scope of certificate monitoring of management systems, SLG is also entitled to carry out short-notice or unannounced audits in justified cases.

(5) Refusal of certification by SLG shall be justified 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 complete re-assessment (like an initial certification) based on a separate order. The same applies in case of failure to apply for re-certification on time.

(6) The client is aware that SLG is awarded specific authorisations by higher bodies which SLG might be deprived of. Should this occur, SLG shall have the right to terminate the contract with the client in whole or in part with regard to the affected authorisations.

Should the authorisations affecting the client be revoked, SLG will also notify the client immediately. SLG advises the client that in the event of authorisations being revoked, it will no longer be able to provide commissioned services (particularly those related to certificate monitoring).

If SLG exercises its special right of termination, it will support the client in the transition to a new certification body or Notified Body.

In the event of withdrawal of SLG authorisations, certificates issued by SLG are affected, the statement of conformity of which includes ongoing monitoring. Further use of the affected certificates by the client is not permitted if and to the extent that the client does not ensure ongoing monitoring by another certification body or Notified Body and provides evidence of this.

In the event of termination of the contract between the client and SLG, the client must enable SLG to fulfill the obligations arising from the transfer to an accepting certification body or Notified Body, provided the statement of conformity includes ongoing monitoring. The accepting certification body or Notified Body must be provided with sufficient information to enable it to make a certification decision.

(7) 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. This is particularly the case if the client refuses to approve auditors or experts and SLG is unable to provide other auditors or experts. In the event of termination, SLG may invoice the client for the costs incurred up to the time of termination.

(8) The SLG enables the client to voluntarily change the certification body or Notified Body and provides sufficient information for this change.

(9) 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.

(10) The client is, however, aware that SLG is obliged to authorised bodies (e.g. authorities, surveillance bodies, accreditation bodies, Committee for Safeguarding Impartiality etc.)

a) to disclose any refused, revoked, withdrawn, restricted, suspended and misused certificates and

b) 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.

(11) SLG shall provide information – if requested – about:

a) geographical areas in which SLG operates,

b) the status of a given certification,

c) the name, basis of certification (relevant normative document), scope and geographical location (city and country) of a specific certified client.

The information regarding certifications mentioned under b) and c) must be made available upon request even after the contract has ended, i.e., even for certifications that are no longer valid. Such information does not constitute a breach of any contractual confidentiality obligations of SLG.

SLG is also entitled to publish the following information about issued certificates on the SLG website:

d) certificate number,

e) date of issue and expiry date,

f) certificate holder,

g) scope and certification basis.

Such publications do not constitute a breach of any contractual confidentiality obligations of SLG.

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

(13) SLG informs certified clients about changes to the certification requirements.

(14) The client is obligated to notify changes requiring approval. SLG evaluates and assesses such modifications to determine whether they are covered by the existing conformity assessment. SLG provides a reasonable conclusion of its assessment to the client.

(15) SLG, as a conformity assessment body, may not disregard any identifiable risks of an object of certification in the certification decision and/or supplement the conformity assessment confirmation and/or the certification agreement with a disclaimer in which certain functions or risks of the object of certification are excluded.

Additional particular features applicable to certification procedures under MDR

(16) With regard to certificates of conformity according to MDR, the SLG points out that

a) certificates according to MDR, including status changes and withdrawal as well as rejection of applications, must be registered and published in the electronic system for Notified Bodies (DMIDS/EUDAMED),

b) SLG fulfils its information obligations according to MDR,

c) certificates can contain conditions and restrictions,

d) certificates can be issued subject to conditions.

(17) Within the validity period of the issued certificate, monitoring activities are conducted at least every 12 months. Furthermore, within the scope of certificate monitoring of QA/QM systems, SLG is authorised, in justified cases, to conduct short-notice or unannounced audits. According to the MDR, unannounced inspections must also be conducted to monitor the proper functioning of the QA/QM system.

According to the MDR, SLG carries out an unannounced audit at random, but at least once every 5 years, at the premises of the client and, if applicable, its suppliers/subcontractors, which is carried out in combination with or in addition to the regular surveillance assessment.

(18) If there is a public interest in the context of certifications according to MDR, SLG may deviate from the obligation of confidentiality regarding results and documents, taking into account proportionality and informing the manufacturer.
In this respect, it is pointed out that the manufacturer must fulfil his information obligations.

(19) According to MDR, as a Notified Body involved in the conformity assessment of a device, SLG may seek the advice of a panel of experts in accordance with MDR Article 106 (11). Before submitting such a request, SLG shall inform the client of this intention.

4. Commitments of the client

(1) The client commits towards SLG in particular:

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

b) to submit all essential documents and procedure documents to SLG. This includes, but is not limited to, documentation regarding the client's QA/QM system. The documents submitted remain with SLG.

c) to support in conducting audits properly 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: The on-site inspection of the site(s) includes, if necessary, remote access to electronic locations containing information relevant to the QA/QM system audit.

d) to 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 if requested by an auditor.

(2) The client is obliged to fulfil the required assurances, in particular

a) to comply with the obligations arising from the approved QA/QM system,

b) to maintain the approved QA/QM system in such a way that its suitability and effectiveness are guaranteed.

(3) The client shall inform SLG immediately about changes that affect the client´s capability to fulfil the certification requirements. Examples of changes may include:

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

b) changes in organisation and management (e.g. key personnel in management positions, decision-making or specialist personnel),

c) changes of the client's contact address and locations,

d) significant changes to the QA/QM system and processes.

Any desired changes to the scope of application covered by the approved QA/QM system must be applied for.

(4) The client must allow observed/witness audits to be conducted by SLG's higher bodies or the participation of auditors in training. This applies to the client's premises, its branches, and its critical suppliers. The client must establish appropriate contractual arrangements with the suppliers.

(5) The client ensures that information related to the certification is not used in such a manner that could bring the certification body and its higher authorities into discredit, and no statements are made that could be regarded as misleading or unauthorised (see also section 5.).

(6) The client undertakes to respect all rights and legal positions of SLG. The client will not do or omit to do anything that discredits or otherwise damages SLG. In particular, the client will not exert any kind of pressure on SLG that is intended to impair SLG's exercise and fulfilment of its obligations.
In the event of a breach of duty, which the client does not cease even after a warning, SLG has the right to terminate the contract with immediate effect. The right to immediate termination with immediate effect in the event of serious breaches of duty by the client remains unaffected.

Additional particular features applicable to certification procedures under MDR

(7) The client of a certification service according to MDR

a) declares that the client has not filed any application with any other Notified Body for certification of its QA/QM system for the same products,

b) indicates if the client has submitted an application for certification of a QA/QM system for the same products, which has been rejected by another Notified Body,

c) indicates if an application by the client for certification of a QA/QM system for the same products has been withdrawn by the client before the final assessment by another Notified Body,

and confirms this in writing with the application.

(8) The client must fulfil his legal obligations under MDR and undertakes to SLG in particular

a) to submit a formal application to the SLG, bearing the signature of the contracting authority and containing all the information and the contracting authority's declaration as required in the MDR Annex relevant for the conformity assessment,

b) to grant unrestricted access to the technical documentation (according to MDR Annex II and III),

c) to provide documentation of all the findings and results obtained from the application of the post-market surveillance plan, including the post-market clinical follow-up plan, to a representative sample of devices and the vigilance provisions laid down in Articles 87 to 92 of the MDR,

d) to submit data provided for in the design part of the QA/QM system, such as results of analyses, calculations, tests and solutions chosen for risk management in accordance with MDR Annex I Section 4,

e) to conclude contractual agreements with suppliers and/or subcontractors which allow on-site audits to be carried out at the premises of the client's suppliers and/or subcontractors; the client must provide support in the organisation,

f) to inform the SLG of serious incidents or serious threats to public health and safety corrective measures taken in parallel with the legally required reports,

g) to comply with its obligation under MDR Article 86 and to submit the resulting periodic safety update report (PSUR) to the SLG,

h) to demonstrate compliance with the requirements of the relevant annexes and, if they no longer in compliance, to take appropriate corrective measures to restore compliance. The deadlines set by the SLG must be observed; otherwise, the certificate may be revoked.

i) to perform incoming, ongoing, and final controls related to preclinical and clinical evaluation, as well as special procedures. If these are missing or insufficient to demonstrate conformity, SLG can request the client to conduct appropriate controls or laboratory tests related to the device.

j) to provide a justification for not having carried out new checks on preclinical assessments, even though conditions in the procedure or the procedure itself have changed.

For certifications under the MDR, the client is the manufacturer. If the manufacturer has appointed an authorised representative in accordance with Article 11 of the MDR, the accepted mandate must be submitted for certification.

(9) With regard to the MDR, the following planned conformity-relevant changes must be approved by SLG by submitting relevant information:

a) changes to the already approved QA/QM system(s),

b) changes to the product range covered by the QA/QM system,

c) changes to the product already approved, in particular to the technical documentation already approved for it,

d) changes by suppliers and/or subcontractors.

In this context, plans for changes, including the expected impact on the currently existing certificate, must be submitted to the SLG.

(10) According to MDR and in connection with a re-certification as well as the renewal of certificates, the client is obliged to submit to SLG a summary of the changes to and the scientific knowledge about the product, which is recorded by the client's QA/QM system, including

a) all changes to the originally approved device, including changes not yet notified,

b) experience gained from post-market surveillance,

c) experience from risk management,

d) experience from updating the proof of compliance with the general safety and performance requirements set out in MDR Annex I,

e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and post-market clinical follow-up,

f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

g) changes to applied or new harmonised standards, specifications or equivalent documents,

h) changes in medical, scientific or technical knowledge, such as

- new treatments,
- changes to test methods,
- new scientific findings on materials and components, including findings regarding their biocompatibility,
- experience from studies on comparable products,
- data from registers and registries,
- experience from clinical investigations with comparable products.

An application for renewal of certificates should be submitted by the client at least 6 months before their expiry.

(11) In order to ensure a targeted execution of unannounced audits in the scope of procedures according to MDR, the client is obliged to inform SLG about periods of production inactivity. This obligation is valid during the whole duration of the corresponding certificate.

5. Rights of use and terms of use

(1) During the validity of the certificate the client may refer in legal transactions to the certificate granted to him and the associated rights of use within the framework of the statutory provisions and other standards and specifications, stating the scope of application and in compliance with the applicable terms of use.

(2) Certificates, document review reports, audit reports, audit protocols and other documents issued by SLG relating to the certification process may not be used in a misleading manner and may only be passed on in their entirety, stating the date of issue.

(3) References to certification status in communication media, such as internet, brochures, advertising materials, or other documents, must always be truthful. Misleading statements regarding certification are prohibited.

(4) If certification is withdrawn, the use of all promotional materials containing references to the certification status must be discontinued. If restricted, all promotional materials must be amended accordingly.

(5) References to system certifications that might imply that the certification body has certified a product (including a service) or a process are not permitted.

(6) Any tacit suggestion that the certification applies to activities and locations that lie outside the scope of the certification is not permitted.

(7) The client is obligated to discontinue reference to the certification or to undergo early recertification even before the expiration of the certificate term if the norms underlying the certification, the standard, or any other requirement document at Levels 4 and 5 (according to EA-1/06) do not longer correspond to the state of the art. To the extent that this is objectively justifiable within the framework of the risk assessment, appropriate transition periods (up to a maximum of three years) may be used for norm or standard conversions.

Should such circumstances occur, SLG is entitled to terminate the agreement with the client in whole or in part by exercising a special right of termination.

(8) SLG is obligated to comply with the "Terms of use and permission (License Conditions) for references to the accreditation status, for the use of accreditation symbols, and other DAkkS property rights by accredited conformity assessment bodies." If SLG becomes aware of a breach of usage rights, it must notify this to the accreditation body (SD-DAkkS-002).

(9) At the client's request, SLG grants the client the right to use the SLG mark for quality management systems. This mark may be used on documents for business correspondence and in advertising. However, it may not be used in connection with the labelling of products (e.g. as an expression of their quality) or on laboratory test reports, calibration certificates, inspection reports, or certificates issued by the client. SLG will inform the client of the specific terms of use and further details, such as the specific graphic representations and language versions. Furthermore, the following applies:

a) Upon receipt of a valid certificate issued by SLG, the certificate holder acquires a simple, temporally and geographically limited, non-transferable right to use the respective SLG mark for quality management systems.

b) The right of use is limited to the information stated in the certificate (among others scope, location, period of validity) and is tied to the validity of the certificate.

c) SLG marks for quality management systems may not be altered. The use of individual components of the SLG marks by the mark user is prohibited as well.

d) Violation of SLG's rights to SLG marks, misuse of the certificate, or misuse of SLG marks may lead to the revocation/withdrawal of the certificate and the rights to use SLG marks. In such a case, SLG has the right to terminate the contract with immediate effect.

e) If the certificate holder becomes aware of any misuse of the SLG mark and/or the issued certificate, the certificate holder must inform SLG immediately.

f) For information purposes, the following examples of graphical representation are provided:

SLG mark for
DIN EN ISO 9001

SLG mark for
DIN EN ISO 13485

Only print templates for SLG marks that are provided by SLG in the course of the individual granting of usage rights may be used.

6. Changes in certificate status

(1) A certificate may be refused, suspended, restricted, withdrawn or revoked, in particular

a) if the requirements for issuing or maintaining the certificate are not met anymore or have not been met at any time,

b) in the event of misuse of the certificates or marks of the SLG or the accreditation body or the appointing/authorising bodies by the client,

c) if deviations or deficiencies in the QA/QM system are identified, which means that conformity with the scope of the certification is no longer guaranteed,

d) if the client refuses surveillance actions,

e) if the client fails to pay fees in due time, previously agreed upon in the contractual agreement and SLG's fee scale,

f) if withdrawal of the certificate is legitimately demanded by authorities or other higher bodies,

g) if compliance with the requirements is not restored by appropriate corrective actions taken by the client authority within a reasonable period of time,

h) in the event of fraudulent behaviour by the client.

SLG justifies its decision towards the client.

(2) In the event of suspension, restriction, withdrawal, or revocation, the rights of use granted and associated with the certificate (see section 5.) shall change to the same extent. In the event of revocation or withdrawal of the certificate, the rights of use shall expire.

(3) Information on the validity of certificates can be obtained from the SLG website.

7. Effective date and modifications to this Regulation for Certification

(1) These Regulations shall become effective on 30 October 2025.

(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 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.