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 legal and regulatory requirements. If applicable, additional accreditation and / or notification regulations are to be observed.

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:

a) Application review: Review of client information and decision on accepting or rejecting the application.

b) Stage 1 Audit: Takes place during initial certification in order to determine whether the organisation is ready for certification.

c) Stage 2 Audit: Conducting 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: Conducting 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 SLG is obliged to consider all information and business secrets that are made accessible to SLG as confidential and to use such information solely for the agreed purpose. The confidentiality of information persists after termination of contract.

3.3 The assessment and certification of the client’s QA / QM system is based on DIN EN ISO 9001, DIN EN ISO 13485, the German Medical Device Implementation Act, the Regulation on Medical Devices (EU) 2017/745 and other relevant standards and directives, depending on the assignment. These activities are conducted by qualified auditors in accordance with the procedures established at SLG and verified by independent bodies.

3.4 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.

3.5 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.

3.6 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.

3.7 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 and the Regulation on Medical Devices, unannounced visits to the certificate holder shall be conducted in order to monitor whether their quality management system is working properly (please see also 5.13).

In accordance with the Regulation on Medical Devices, SLG conducts an unannounced audit at random, but at least every 5 years, at the client's location and if necessary at the location of suppliers / subcontractors which are combined with the regular surveillance or in addition.

3.8 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.

3.9 Refusal of certification by SLG shall be accompanied to the client by a 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 (like an initial certification) based on a separate order. The same applies in case of failure to apply for re-certification in good time.

3.10 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.

3.11 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.

This could be the case, for example, if the client refuses to approve external auditors or experts and SLG is not able to provide another external auditor or expert. SLG may withdraw from the contract and invoice the costs incurred up to that point.

3.12 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.

3.13 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, Committee for Safeguarding Impartiality 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.

3.14 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).

3.15 In case of certifications according to the Regulation on Medical Devices, the client is also obliged to comply with its information obligations, in particular:

If there is a public interest, SLG may deviate from the principle of confidentiality regarding test results and documents, taking into account proportionality and informing the manufacturer.

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

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

3.18 In accordance with the Regulation on Medical Devices, the client is obliged to inform SLG about modifications subjected to approval. SLG evaluates and assess such modifications whether the QM system is still covered by the existing conformity assessment. SLG provides a reasonable conclusion to the client.

SLG issues the approval of a significant change to the QM system or the range of products covered by it in the form of a supplement to the EU quality management system certificate.

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. Legal requirements about content and validity of the certificate shall be considered (e.g. according to Regulation on Medical Devices Annex XII).

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 3.8.

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,

f) the fulfilment of the requirements could not be re-established by suitable corrective actions within an appropriate timeframe.

The suspension, restriction or withdrawal is conducted taking into account the principle of proportionality.

SLG justifies its decision towards the client.

4.4 In any case, the certificate holder shall be informed about changes of the certificate status (according to paragraph 4.3, among others) and their reasons.

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

4.6 SLG points out that

a) certificates according to the Medical Product Directive, including status changes, are registered in the public area of DMIDS/EUDAMED database,

b) certificates according to the Regulation on Medical Devices, including status changes and withdrawals as well as rejections of applications, must be registered and published in the electronic system for Notified Bodies (DMIDS/EUDAMED),

c) SLG may publish certificates issued at www.slg.info which are based on SLG's own certification procedures,

d) SLG fulfils its information obligations in accordance with the Regulation on Medical Devices,

e) in relation to certificates according to the Regulation on Medical Devices,

- SLG may limit the intended purpose of a product to specific patient groups,
- the client may be required by SLG to carry out specific post-market clinical follow-up studies according to Annex XIV Part B.

4.7 According to the Regulation on Medical Devices Art. 120 (transitional provisions), every notification of a Notified Body in accordance with the Medical Devices Directive was formally invalid from 26.05.2021.

The certificates issued remain valid until the end of their validity, at the latest until 27.05.2024, "provided there are no significant changes in the design and purpose".

The (former) Notified Body still has the duty to conduct surveillance activities for certificates issued by the Notified Body according to the Medical Devices Directive. However, the requirements of the Medical Devices Regulation on "post-market surveillance, market surveillance, and vigilance, registration of economic operators and of devices" then apply to these surveillances.

5 Commitments of the Client

5.1 The client commits towards SLG in particular:

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

b) to submit all essential documents and procedure documents to the auditors appointed by SLG. That includes in particular but non-exclusively:

- the documentation of its quality management system,
- documentation of all findings and results obtained from the application of the post-market surveillance plan, including the PMCF plan, to a representative sample of devices, and of the vigilance provisions set out in the Regulation on Medical Devices Articles 87 to 92,
- the data provided for in the design part of the quality management system, such as results of analyses, calculations, tests and solutions chosen for risk-management according to the Medical Devices Regulation Annex I Section 4.

All documents submitted remain with SLG. Documents of which copies are made by SLG will be charged to the client.

c) to support SLG 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: 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.

On-site-audits may also affect premises of the client’s suppliers and / or subcontractors. The client must support the organisation of such audits.

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 as requested by an auditor.

5.2 The client is obliged to fulfil all legally required assurances, in particular:

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

b) to keep the approved QA/QM 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,

d) to obligations relating to the use of conformity marks according to current legislation as well as information related to the product; this also applies to the use of CE marking, including the rules for using the number of the Notified Body specified in the relevant legislation.

5.3 The use of the QM system marks according to DIN EN ISO 9001 and DIN EN ISO 13485 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 immediately about changes that affect the client´s capability to fulfil the certification requirements.

Note: Examples of changes may include:

- changes of the legal, economic or organisational status or ownership,
- changes of organisation and management (e.g. key managing personnel, decision makers or experts),
- changes of the client's contact address and locations,
- changes of critical suppliers / subcontractors.

5.5 According to the Regulation on Medical Devices, the following planned changes must be approved by the SLG on an ongoing basis by submitting relevant information :

a) changes on the already approved quality management system(s),
b) changes of the product-range covered by the quality management system,
c) changes on the product that has already been approved, in particular the technical documentation that has already been approved for it.

In this context, plans for the change including the expected impact on the prior approval must be submitted to SLG.

5.6 According to the Regulation on Medical Devices 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 QM system:

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 the Regulation on Medical Devices Annex I,
e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and post-market clinical follow-up (PMCF),
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, common specifications or equivalent documents and
h) changes in medical, scientific and technical knowledge, such as:
   - new treatments,
   - changes in test methods,
   - new scientific findings on materials and components, including findings on their biocompatibility,
   - experience from studies on comparable devices,
   - data from registers and registries and
   - experience from clinical investigations with comparable devices.

An application for renewal of certificates should be submitted by the client no later than 6 months before they expire

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

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

5.9 The client shall inform SLG immediately about any recalls, any serious incidents or serious risks to public health as well as measures that have been initiated.

5.10 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 for the same product(s). According to the Regulation on Medical Devices, the client shall provide that information together with the application in writing.

5.11 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.

5.12 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.

5.13 In order to ensure a targeted execution of unannounced audits in the framework of procedures according to Medical Devices Directive and the Regulation on Medical Devices, the client is obliged to inform SLG about periods of production inactivity. This obligation is valid during the whole duration of the corresponding certificate.

5.14 In case of certification in accordance with the Regulation on Medical Devices, the client is also obliged to comply with its information obligations, in particular:

a) when commissioning SLG, to submit a formal application that bears the client's signature contains all information and the client's declaration, as stipulated in the Annex of the Regulation on Medical Devices which is relevant for the conformity assessment;

b) For certifications according to the Regulation on Medical Devices, the client shall be the manufacturer. Note: If the manufacturer has appointed an authorised representative, the accepted authorised representative's mandate as per Regulation on Medical Devices Article 11 shall be submitted for certification.

c) to inform SLG about vigilance reports;

d) to submit the resulting, regularly updated safety report (PSUR) to SLG, as the client is obliged according to the Regulation on Medical Devices Article 86;

e) to demonstrate compliance with the requirements of the relevant Annexes of the Regulation on Medical Devices and, if no longer in compliance, take appropriate corrective measures to restore compliance. The deadlines set by SLG must be observed, otherwise there is a risk of the certificate being lost.

f) to perform incoming, ongoing and final checks related to pre-clinical and clinical evaluation and special procedures. If these are missing or insufficient to demonstrate conformity, SLG can request the client to conduct appropriate checks or laboratory tests with regard to the product.

g) to provide a justification for not undertaking new studies related to pre-clinical assessments, even though conditions in the process or the process itself have changed;

h) to submit to SLG an appropriate plan (in accordance with the Regulation on Medical Devices Annex XIV Part B) that addresses the post-market clinical follow-up of the product to demonstrate the safety and performance of the product (if applicable);

i) to provide evidence of adequate control of its suppliers. Otherwise, the on-site inspection of the supplier's processes must also be included by SLG in the current audit programme.

j) to grant SLG unrestricted access to the technical documentation (according to the Regulation on Medical Devices Annexes II and III);

k) to provide SLG with clear evidence if no clinical trial was carried out because the product has already been placed on the market and all conditions in accordance with the Regulation on Medical Devices Chapter VI Article 61 (5) have been met (if applicable);

l) In case of public interest, it is possible to deviate from the principle of confidentiality regarding test results and documents, taking into account proportionality informing the manufacturer in advance.

5.15 The client is aware that SLG as an accredited, notified, recognised body is entitled to issue certificates within the scope of accreditation, notification, recognition. This does not mean that the accrediting, notifying, recognising body is responsible for the result of the certification.

5.16 The client ensures that information related to the certification is not used in such a manner that could bring the certification body and it higher authorities into disrepute, and no statements are made that could be regarded as misleading or unauthorised.

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 Effective date and modifications to this Regulation for Certification of QA/ QM systems

8.1 These Regulations shall become effective on 23.01.2023.

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.