Regulations for Testing and Certification of Products of SLG Prüf- und Zertifizierungs GmbH

1 Scope

These Regulations for Testing and Certification apply for all product tests and certifications, as well as surveillance measures, 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 Commitments of SLG

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

2.2 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.

2.3 The client is, however, aware that SLG is obliged to disclose any refused, revoked, withdrawn, restricted, suspended and misused certificates to authorised bodies (e.g. authorities, accreditation bodies, surveillance bodies, Committee for Safeguarding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.

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

2.5 The certification body of SLG is obliged to inform the certificate holder of GS certificates about changes of legal provisions and other regulations that are relevant for the approval holder.

2.6 SLG checks and evaluates any changes communicated by the client and requiring approval in accordance with the Regulation on Medical Devices in order to determine whether these changes can affect the conformity of the product with the basic safety and performance requirements or with the intended conditions of use of the product. SLG informs the client of its decision.

SLG issues the approval of a significant change to the already approved product in the form of a supplement to the EU type examination certificate.

3 Regulations for Testing

3.1 The client files an application to SLG for product testing and product certification within the scope of the Product Safety Act (ProdSG) for GS mark approval, within the scope of a conformity assessment procedure in accordance with valid regulatory requirements for CE marking of the product or within the scope of other product certification schemes.

3.2 Commissioning of testing services without connected certification services is also possible. Paragraph 4 does not apply in such a case.

3.3 At the latest when the contract is concluded, the client shall submit one or several samples of the item to be tested to SLG as well as all documents required for conducting the product tests. This includes in particular all documents referred to in SLG's quotation and further documents forming the basis of the contract.

In accordance with the Regulation on Medical Devices, SLG may request further copies of the type test sample and must request a written declaration from the client that no parallel application for the same type has been submitted to any other Notified Body, or information about any applications for the same type that were rejected by another Notified Body or were withdrawn by the client before the final assessment by the other Notified Body.

3.4 All documents submitted remain with SLG. The client is responsible to copy them for their own records.

3.5 The test procedure starts after delivery of the test sample(s) and all required documents.

3.6 The items to be tested shall be specified with regards to their design type, current, voltage and output. Circuit and construction diagrams shall be provided, and if applicable, a statement concerning the intended purpose and product classification. In case the certification process involves a factory inspection the application documents shall include a completed Factory Inspection Questionnaire. Forms are available at SLG.

3.7 The tests are conducted in the test laboratories of SLG, in the laboratories of SLG's cooperation partners or at the premises of the manufacturer. SLG determines the actual test location, whereby the specifications of the certification scheme need to be considered if tests are performed within such a certification scheme.

3.8 After completion of the test procedure the client receives a test report and an invoice. In case of a positive test result and compliance with all other requirements a certificate may be issued on application. In addition, paragraph 4 applies.

3.9 As a general procedure, the testing body labels all submitted test samples upon delivery, and after testing, either places them in storage (see paragraph 4.3) or returns them to the client at the latter's expense.

3.10 SLG shall not be liable for the loss of test samples or for damages to test samples through no fault of their own caused during the testing period, e.g. as a result of burglary, theft or damage by fire or water.

3.11 In the event of a separate agreement, SLG will provide additional testing and evaluation services for the client. Client-specific wishes requirements may be considered, provided that they do not conflict with any regulatory requirements, regulations and standards.

3.12 SLG is accredited by DAkkS according to DIN EN ISO/IEC 17025. The scope of accreditation is published on the DAkkS website as well as on SLG's website. Test reports showing the DAkkS accreditation symbol are issued within the accreditation. Test reports without an accreditation symbol are issued outside the accreditation.

4 Regulations for Certification

4.1 The client ensures that:

4.1.1 certification requirements are always fulfilled, including product requirements, determined by the certification scheme. In case of certification according to legislation, this concerns compliance with the regulatory requirements of the respective legally regulated conformity assessment procedure;

4.1.2 appropriate changes communicated by the certification body are implemented;

4.1.3 if the certification applies to ongoing production, the certified product continues to fulfil the product requirements;

4.1.4 all necessary arrangements are made for

- the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records (including reports on internal audits), and access to the relevant equipment, location(s), area(s) and personnel, and
- investigation of complaints;

4.1.5 claims are made regarding certification consistent with the scope of certification;

4.1.6 product certification is not used in such a manner as to bring the certification body and the certification body´s higher authorities into disrepute and no statement is made regarding the product certification which the certification body may consider misleading or unauthorized;

4.1.7 upon suspension, withdrawal, or termination of certification, any use of all advertising matter that contains any reference thereto is discontinued and any certification documents as required by the certification scheme are returned and any other required measure is taken;

4.1.8 if the client provides copies of the certification documents to others, the documents are reproduced in their entirety or as specified in the certification scheme;

4.1.9 in making reference to the product certification in communication media such as documents, brochures or advertising, requirements of the certification body or as specified by the certification scheme are complied with;

4.1.10 any requirements that may be described in the product certification scheme are complied with that relate to the use of marks of conformity in accordance with valid legal and regulatory requirements, and on 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;

4.1.11 a record is kept of all complaints made known to the client relating to the compliance with certification requirements and these records are made available to the certification body when requested; and

- appropriate action is taken with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;
- the actions taken are documented;

4.1.12 the certification body (SLG) is informed by the client, without delay, of changes that may affect its ability to conform with the certification requirements.

NOTE: Examples of changes can include:

- the legal, commercial, organizational status or ownership,
- organization and management (e.g. key managerial, decision-making or technical staff),
- modifications to the product or the production method,
- contact addresses and production sites,
- scope of operations in the production method.

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

- changes in the product design,
- changes in the intended use of the product,
- changes in product information,
- changes of the approved type of a product.

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

4.1.14 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 changes and scientific findings about the product, including

- all changes to the originally approved device, including changes not yet notified,
- experience gained from post-market surveillance,
- experience from risk management,
- experience from updating the proof of compliance with the general safety and performance requirements set out in the Regulation on Medical Devices Annex I,
- experience from reviews of the clinical evaluation, including the results of any clinical investigations and post-market clinical follow-up (PMCF),
- changes to the requirements, to components of the device or to the scientific or regulatory environment,
- changes to applied or new harmonised standards, CS or equivalent documents and
- 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.

4.2 In case the certification process involves a surveillance of the production, SLG shall conduct an initial factory inspection at the client's expense in order to check whether technical equipment and human resources at the facilities are organised and managed in such a way that a consistent quality can be maintained and the compliance of the production with the sample to be certified can be guaranteed.

4.3 If SLG's certification scheme requires the storage of test samples, reference samples are kept after certification, either placed in safe storage or, if requested by the client, returned at the client's expense. In the latter case, the client must make the test samples available to the testing body at any time upon first request or send them to SLG free of charge upon first request. The client is obliged to keep the reference samples and associated documents for the validity period of the certificate. SLG prepares sufficient documentation for the test samples.

4.4 SLG shall state their reasons for rejecting a requested certification to the client in writing. SLG shall not be liable for any disadvantages the client experiences from such refusal. Any new application submitted later than six months after the rejection shall require a completely new test including a new application / order.

4.5 SLG laboratories are not considered external resource and are therefore not subject to confirmation by the client.

4.6 If the client refuses to agree to the use of external experts and if SLG is not able to provide any other external expert, SLG is legitimated to withdraw from the contract and invoice the costs incurred up to that point.

4.7 Clients who have received a certificate shall become partners in SLG's certification programme and thus, certificate holders. The client is therefore subject to regular control checks by SLG, should the certification programme provide for surveillance measures.

4.8 Upon application by the client or on their own initiative, SLG may conduct the following tests and take the following measures:

- retests in case of standard changes in order to ascertain compliance of the formerly approved products with the new stipulations,
- inspections (random checks) of approved products to ascertain whether the latter comply with the requirements,
- pre-shipment inspections,
- production inspections (also lot-by-lot),
- restriction of certificate scopes to production lots.

4.9 The entitlement to use the test mark shall apply solely to the certificate holder, and exclusively relates to those production facilities and products stated on the certificate. The certificate shall be valid for the period stated on the certificate.

4.10 For maintaining certificates, which are subject to surveillance, advance payment of fees shall be effected in accordance with the contractual stipulations and the SLG fee scale. The payment entitles the client to use the given mark in accordance with the SLG Mark Statute within the calendar year for which payment has been effected.

4.11 The SLG Mark Statute contains in detail the rights to use SLG marks. The mark statute may be sent to the client on request. It can also be viewed at "www.slg.de.com".
A granted test mark does not imply a statement on the marketability of the certified product.

4.12 The certificate holder shall constantly ensure that the production of the certified products complies with the test stipulations and shall conduct the checks determined during the factory inspection (surveillance checks and checks of single items) in due form. The certificate holder allows the authorised authority ZLS to participate in a factory inspection as an observer following an announcement.

4.13 The awarded certificate and an entitlement to use test marks derived thereof shall only be valid if the client is able to provide proof that all requirements are fulfilled which are to be observed by the latter during the production of technical equipment and consumer products ready for use in order to guarantee their compliance with the tested sample. All changes in technology and design require the consultation and approval of SLG. In case of unacceptable deviations the awarded certificate and the entitlement to use test marks derived thereof shall not be valid for the modified products. Furthermore, SLG shall be entitled to take measures according to paragraph 4.17.

4.14 On the occasion of the initial factory inspection performed at the expense of the applicant, a report shall be prepared and a cycle for the routine inspection of the production or check of the certified products (follow-up service) shall be specified by SLG. After each regular factory inspection or product check the certificate holder shall receive a report on the findings.

4.15 In order to ensure that the characteristics named on the certificate are sustained the certification body is entitled to conduct regular checks on samples taken from the production line according to the contractual basis at the expense of the client. The certification body may take out products from the warehouse of the client for surveillance purposes free of charge or by third parties at their expense. In case of not fulfilling the technical requirements the certificate holder shall bear all costs.

4.16 Certificates subject to surveillance shall expire in case the certificate holder terminates the mark approval by November 15th of the current year or if the rules of technology forming the basis for the certificate no longer justify a presumption of conformity or if the standards stated on the certificate have changed as much that the presumption of conformity expires.

4.17 The certificate including the entitlement to use test marks derived thereof may be withdrawn, suspended, restricted or revoked by the certification body if

- it contravenes the legal provisions and current decisions of the working groups (Erfahrungsaustauschkreise) of the certification bodies / Notified Bodies (among others ProdSG: ZEK and EKs, notifications / FAQ by ZLS, official orders by ZLS, the German Medial Device Implementation Act - MPDG, the Regulation on Medical Devices, EK-Med, official orders by ZLG, CB Scheme: CMC and CTL Decision Sheets),
- the client uses the test / certification mark for inadmissible advertising purposes,
- defects not detectable at the time of the test become evident at a later date,
- the products labelled with the test mark differ from the approved test samples,
- the certificate holder refuses the performance of factory inspections,
- the certificate holder does not allow SLG to visit production facilities, inspect test equipment or assess the products,
- deficiencies are found in quality assurance and the fulfilment of the requirements could not be restored by suitable corrective measures by the manufacturer within a reasonable period of time,
- the client fails to pay fees by their due date,
- compliance with the tested samples can no longer be guaranteed.

As a result of any measures taken by SLG the certificate holder shall forfeit his entitlement to continue identifying products with the test mark.

A declaration of invalidity of the certificate and the authorisation to use the test mark may be published by SLG or must be published by SLG if this is required by law.

4.18 The certificate holder shall be informed about an intended change of the certificate status (according to paragraph 4.17) and the reason for the change.

4.19 In order to renew certificates the certificate holder must apply in due time (six months before the expiry of the certificate) and provide the information required in the certification scheme.

4.20 The certificate holder is aware that

- SLG publishes a list of issued GS certificates as required by ProdSG on the following website: www.slg.info;
- in compliance with ProdSG, SLG publishes information regarding the misuse of GS marks granted by SLG on the website: www.slg.info,
- CB certificates are registered in the public area of the IECEE database,
- SLG may publish certificates issued on the basis of SLG owned certification schemes on the website: www.slg.info,
- certificates according to the Medical Devices Directive, including status changes, are registered in the public area of the DMIDS/EUDAMED database,
- 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),
- SLG fulfils its information obligations in accordance with the Regulation on Medical Devices,

- in relation to certificates of conformity according to the Regulation on Medical Devices,
  - SLG may limit the intended use of a product to certain patient groups,
  - it may be required by SLG to carry out certain post-market clinical follow-up studies in accordance with Annex XIV Part B.

4.21 The client has the right to file objections or complaints with SLG in particular against SLG's decisions and determinations. Objections and complaints shall be processed in accordance with the procedures specified in SLG's QM system.

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

- 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;
- For certifications according to the Regulation on Medical Devices, the client shall be the manufacturer. 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.
- to inform SLG about vigilance reports.
- 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;
- 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.
- to submit a new application for the conformity assessment in the event of changes to the intended purpose and the conditions of use of the approved product;
  This also applies to a type examination that has already taken place.
- 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.
- 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;
- 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);
- to grant SLG unrestricted access to the technical documentation (according to the Regulation on Medical Devices Annexes II and III);
- 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);

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.

4.23 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.

4.24 If the requirements of the Regulation on Medical Devices are not met anymore by the client, issued certificate may be suspended, restricted or withdrawn by SLG. The suspension, restriction or withdrawal is conducted taking into account the principle of proportionality.

SLG justifies its decision towards the client.

4.25 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 imitated.

4.26 The client is aware that the SLG has been granted special competences by higher bodies and that these competences can be revoked. If this occurs, SLG will inform the client immediately. Otherwise, the existence of the competences is considered the business basis of the contract concluded between SLG and the client for certification services. If the business basis no longer applies, SLG is not obliged to provide further certification services. The SLG will support the client in the transition to a new accredited / Notified Body. In case the business basis of the contract is no longer applicable, the client has no claims against SLG in this regard.

4.27 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 Publication of test and certification documents

Test and certification documents and expert reports shall only be reproduced in their complete wording and with the date of issue specified. A publication in part shall require written approval by SLG. SLG holds all proprietary rights on aforementioned documents.

6 Infringements of the Regulations for Testing and Certification

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.

7 Effective date and modifications to these Regulations for Testing and Certification

7.1 These Regulations shall become effective on 23.01.2023.

7.2 The present Regulations for Testing and Certification are subject to constant changes, e.g. due to changes of legal conditions, accreditation regulations as well as the generally acknowledged rules of technology and relevant standards and directives. Therefore, in each case the current version of these regulations shall apply.