

Examination regulations of Berlin Cert

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Governing Language

The original version of these examination regulations is in German. In the event of any discrepancies or differences between the German version and any translations of these Terms and Conditions, the German version shall prevail and be binding.

§ 1 Definitions

The following definitions are used below:

Berlin Cert refers to the certification body and notified body "Berlin Cert GmbH," which is accredited by the German Accreditation Body (DAkkS) and designated by the Central Authority of the German States for Health Protection in Medicines and Medical Devices (ZLG) (CE 0633). The scope of accreditation and designation can be viewed at any time on the Berlin Cert website and the websites of the respective approving bodies.

Contractual partner refers to any legal entity that applies for certification, is party to the contracts to be concluded, or holds one or more certificates from Berlin Cert. In a certification process, several legal entities may also jointly seek or hold certification. The examination regulations described here apply to each of these individually, while the specific conditions specify the entire certification procedure.

Specific conditions refer to the contractual conditions that specify these examination regulations. They consist of an offer, one or more technical contract appendices relating to the selected standard(s), and, if applicable, updated cost calculations.

Certification comprises all testing and assessment activities, the result of which is a formal confirmation of compliance with specified requirements.

Conformity assessment comprises all testing and evaluation activities that result in formal confirmation of compliance with specified regulations or laws.

§ 2 Test object

By submitting its offer and provided that all necessary requirements for an audit have been met, Berlin Cert agrees to carry out an assessment of the subject of the audit specified therein with the aim of issuing one or more audit certificates, hereinafter referred to as certificates or attestations, on the basis of one or more standards, regulations, or laws. This includes the right to use the associated certification marks in accordance with the provisions set out in these examination regulations.

The exact scope of this contract with regard to the choice of standard(s), the locations involved and, if applicable, different legal entities, as well as the activities of the contractual partner is regulated in the offer and/or the technical annex to the contract.

§ 3 Tasks of Berlin Cert

(1) Conducting the examination

Berlin Cert carries out the agreed audits in accordance with the provisions and requirements of the accreditation/designation and the normative principles/regulations specified in the Specific Conditions. The components of the procedure are agreed with the contractual partner.

In order to maintain the validity of certain tests and certifications, Berlin Cert must regularly evaluate the effectiveness of the test object. The necessary checks are carried out in accordance with the Specific Conditions.

Due to its obligations as an accredited testing organization, Berlin Cert is entitled to allow observers from accreditation bodies or organizations with similar tasks (system owners, technical supervisors) to participate in the testing. Berlin Cert also has the right to send its own observers to tests for the purpose of quality assurance. If this occurs, Berlin Cert will inform the contractual partner in good time.

Berlin Cert is entitled to carry out unannounced and short-notice audits at the company if this appears necessary to maintain certification, e.g., following complaints from third parties.

(2) Deployment of auditors

The persons commissioned to carry out the audit will be named to the contractual partner by Berlin Cert. In the event that an auditor is unable to attend immediately before or during an audit, Berlin Cert will appoint a representative. Berlin Cert may appoint observers from the accrediting or designating organization, or trainees for its own training purposes.

The contractual partner has the opportunity to cite reasons that speak against the use of an auditor. These reasons must be communicated to Berlin Cert immediately after the names of the auditors have been announced. In such cases, Berlin Cert will examine whether the reasons given are sufficient to change the auditor and will inform the customer of this decision. When appointing a replacement auditor, Berlin Cert will take particular care with regard to the reasons given by the customer.

The contracting party may cite such reasons once. Observers may not be rejected in accordance with paragraph 1.

If no reasons for rejection are communicated within 10 days of the announcement of the auditors, the proposal shall be deemed accepted. Upon request, the contractual partner undertakes to inform the auditors truthfully, promptly, and completely about all facts and events that are relevant to the audit.

(3) Completion of the audit

Berlin Cert shall prepare a results report for each audit (this term covers all subsequent audits), which shall be made available to the contractual partner. Berlin Cert shall retain ownership of these reports. Although pseudonymization is preferred, personal data may be recorded in the report and in the documentation of the audit process.

If, after the audit, all necessary requirements have been met and the audit basis provides for it, Berlin Cert will issue a certificate/attestation.

If, after the audit has been carried out, not all requirements for the issuance of a certificate/attestation have been met, reports are prepared in which the deviations are recorded or conditions are announced that are necessary to obtain the certificate. The deadline for rectifying the deviation is agreed with the auditor and may not exceed the statutory deadline.

Once the deviations have been rectified within this period, Berlin Cert will verify the effectiveness at its discretion by checking the documents submitted or conducting an on-site re-inspection.

If the deficiencies cannot be remedied within this period, Berlin Cert reserves the right to decide whether to carry out a new re-inspection.

If the requirements are still not met after two re-inspections, the certificate cannot be issued. A new certification procedure must then be carried out as an initial certification.

(4) Certificates

Certificates and certification documents remain the property of Berlin Cert and may not be transferred, assigned, or altered in any way. Validity begins at the earliest on the day on which the relevant decision is made by the person responsible for the audit.

The certificate(s) refer only to the activities/products and locations listed in the Specific Conditions and confirmed as a result of the audit.

Berlin Cert is obliged to keep records of the certificates it has issued, suspended, and withdrawn and to publish them with the name of the contractual partner, address, certified standard, and scope of validity. In justified exceptional cases (e.g., for security reasons), the contractual partner may request a restriction of the information to be published. However, Berlin Cert is obliged in all cases to state the status of a submitted certificate.

§ 4 Tasks and rights of the contractual partner

(1) Cooperation of the contractual partner

The cooperation of employees and management of the client is required for the audit to be carried out. The contractual partner shall therefore appoint a responsible contact person who will be available for queries and discussions throughout the entire process.

Unless otherwise agreed with the audit manager, the contractual partner shall provide each auditor with an accompanying person for the duration of the audit. It must be ensured that the accompanying persons neither hinder nor influence the audit.

The contractual partner undertakes to

- to provide Berlin Cert, upon request, with all documents necessary for the implementation of the procedure in a timely manner, i.e., as a rule, no later than six weeks before the implementation of the audit, free of charge, and to provide complete and truthful information,
- that Berlin Cert is given access
 - to all relevant documentation and records, the equipment required for the activity (e.g., devices, machines, or measuring equipment),
 - to the relevant locations and areas,
 - to the responsible personnel, and
 - any subcontractors, if these fall within the scope of the audit.
- to inform Berlin Cert personnel of all health and safety rules to be observed, as well as the relevant laws and regulations, and to provide the necessary equipment for the audits. Berlin Cert personnel are obliged to comply with these.

- make every effort to support the proper conduct of the audits by Berlin Cert, in particular to provide the auditors with truthful, timely, and complete information on all facts and processes relevant to the audit when asked.
- to inform Berlin Cert of previous certification and/or assessment procedures, including the results, insofar as these are relevant to the commissioned audit.
- Upon request, to provide Berlin Cert with the names of organizations or persons who have provided consulting or similar services to the contractual partner.
- to record all complaints concerning compliance with the certification requirements and to make these records available to Berlin Cert upon request. In addition, the client must take appropriate measures in relation to these complaints and to any identified deficiencies in the products that affect the certification requirements, and must document the measures taken in a comprehensible manner.
- Not to submit a parallel application to any other body in relation to the specified products and systems, or to have submitted an application that is still pending.

(2) Deployment of auditors

The contractual partner undertakes to refrain from any action that could jeopardize the independence of the auditors. This applies in particular to consulting activities or employment, orders for their own account, or separate fee agreements.

The contractual partner is obliged to disclose to Berlin Cert any situation known to it that could place itself or Berlin Cert in a conflict of interest. Such conflicts of interest may arise in particular if auditors commissioned by Berlin Cert perform or have performed consulting activities for the contractual partner or if other business relationships exist.

(3) Changes regarding the subject matter of the audit, maintenance

The contractual partner undertakes to inform Berlin Cert immediately of any changes that are in any way relevant to the audit.

The contractual partner must ensure that the certified subject of the audit always meets the requirements of the certified standard(s) – even during transition periods. The various statuses of the system must be identified and followed. In cases of doubt, the contractual partner must inform Berlin Cert of any problems in connection with changes in order to find a solution together.

After taking note of this, Berlin Cert shall decide in consultation with the contractual partner whether an additional audit is necessary to maintain or change the certificate.

The contractual partner is obliged to regularly carry out measures to maintain the subject of the audit and to document these in a verifiable manner. They are also obliged to keep records of complaints from customers and other interested parties, in particular with regard to audit-relevant issues or their management system.

Berlin Cert shall inform the contractual partner of any changes to the certification requirements. This may take the form of a customer letter (also by email) or other publications.

The contractual partner is obliged to implement the changes communicated by Berlin Cert. This will be checked in the next audit (review or recertification).

(4) Right of complaint and objection

The contractual partner has the unrestricted right to complain and appeal. The description of the complaint and appeal procedure is publicly available.

§ 5 Use of certificate and certification mark

(1) Right of use

If provided for in the audit procedure, Berlin Cert will issue the contractual partner with the corresponding certificate upon successful completion of the certification procedure. The certificate is valid for the term specified therein. The right of use expires upon expiry of the certificate term.

Upon issuance of the Berlin Cert certificate, the contractual partner acquires the simple, non-transferable, and non-exclusive right to use the certificate and the corresponding Berlin Cert certification mark during the term of the certificate in accordance with the provisions of this document and the Specific Conditions.

"Use" of the certificate or certification mark is understood to mean the identification of the certificate/mark or the nature of the certification to third parties. Third parties in this sense are all natural and legal persons and associations of persons, and in particular the public and the general public, except for the contracting party and Berlin Cert itself.

Berlin Cert does not guarantee that the certification marks can be used without restriction for the purposes of

(2) Scope of use

(2) Scope of use

The scope of the contractual partner's certification is described in the certificate. It contains detailed information on the type and scope of certification, in particular the company name and the locations or products included. The use of the certification marks is limited to this and may not be used for subsidiaries, affiliated companies, or locations that are not included in the certificate.

(3) Type of use

- 1) Berlin Cert certification marks may only be used by the contractual partner and only in direct connection with the contractual partner's company name or logo.
- 2) The contractual partner may only disclose the audit report in its entirety and with the prior approval of Berlin Cert. All relevant content must be comprehensible to third parties.
- 3) The contractual partner is obliged not to make any statements or declarations regarding its certification that could be considered misleading or unauthorized by Berlin Cert or third parties.

- 4) The contractual partner undertakes to comply with the requirements listed by Berlin Cert when referring to its certification status in communication media (internet, brochures, advertising materials, etc.).
- 5) Unlike the certification mark, the accreditation and designation mark may not be used on documents for business or commercial purposes. It may only be used in the form of a copy of the certificate/certification.
- 6) The certification may not be used in a manner that discredits the certification body and/or the certification system.
- 7) Certification marks are made available to the contractual partner by Berlin Cert. They may only be used in the form available there. The contractual partner is not entitled to make any graphic changes to the certification marks. The marks must be easily legible. The contractual partner will be informed separately about any further specific conditions for the use of certification marks.

If you have any questions or problems, the print design and use of certificates and certification marks can be coordinated with Berlin Cert.

(4) Expiration of the certification mark

The right of use is linked to the validity of the certificate issued. The right of use expires automatically when the term specified in the certificate has expired or when verification audits are not successfully completed. It expires with immediate effect if the certificate(s)/certification(s) pursuant to § 6 is/are suspended, canceled, or revoked or if the contract is terminated extraordinarily pursuant to § 9. In the event of ordinary termination, the right of use shall end upon expiry of the notice period. The right of use shall expire automatically if the maintenance of the certificate is prohibited by regulatory or judicial means.

Upon expiry of the certificate/certification, the contractual partner may no longer use or distribute any remaining documents, media, etc. bearing the certification mark. The requirements for non-use are deemed to be fulfilled if the certification mark is completely covered. For certification marks, e.g. on vehicles, containers, and other movable goods that are not within the immediate sphere of influence of the contractual partner at the time of termination of the right of use, an extended period of one week applies.

(5) Indemnification against third-party claims due to use in breach of contract

If Berlin Cert is held liable under product liability principles due to use of the certification in breach of contract, the contractual partner is obliged to indemnify Berlin Cert against all third-party claims. The same applies in cases where Berlin Cert is held liable by third parties due to advertising statements made by the contractual partner.

§ 6 Changes, suspension, and withdrawal of certificates

Certificates that have been issued may be changed based on the results of an audit. In the event of a restriction of the scope of validity, the use of the certificate or certification mark must be adjusted immediately.

Berlin Cert may suspend certificates that have been issued if

- the specified period for completing the review process is exceeded, or
- the client's certified management system does not meet the requirements even after the specified deadline for corrective measures has expired, or
- the monitoring or recertification audits cannot be carried out at the required frequency or are not permitted, or
- the client voluntarily requests a suspension, or
- insolvency proceedings have been opened against the client or have been discontinued due to lack of assets, or
- despite reminders, Berlin Cert's claims are not paid in full, or
- legal provisions or official requirements are not or no longer complied with, or
- deficiencies in the system are identified or essential requirements of the certified system are not or no longer met, or
- a product marked with a Berlin Cert GmbH mark or a CE mark with reference to a Berlin Cert GmbH certificate of conformity does not correspond to the approved type or is no longer manufactured, or
- an unannounced audit at the customer's premises or at one of its important suppliers and subcontractors cannot be carried out or cannot be carried out successfully, or
- the removal of products for inspection is refused.

The suspension shall be notified in writing, together with the requirement to cease advertising with the certificate or certification mark until the suspension is lifted
advertising with the certificate or certification mark or otherwise
refer to the certification. The suspended certification must be reinstated
once the problem that led to the suspension has been resolved.

It may be suspended for a maximum period of 6 months. A verification audit will be carried out for resumption. Upon successful completion of the verification procedure, the suspension will be lifted and the existing certificate will become valid again. If the problems leading to the suspension have not been resolved after the specified period, the certificate may be withdrawn or its scope restricted.

A certificate must be withdrawn by the certification body if

- a suspension of a certificate cannot be lifted on time, or
- the client voluntarily does not wish to maintain certification, or
- the client permanently ceases its activities, or
- the contractual partner terminates the certification contract in accordance with § 9 .

The client will be requested in writing to return the certificate and to refrain from any further advertising with the certificate or the certification mark or otherwise referring to an existing certification.

§ 7 Market control

Berlin Cert GmbH may at any time remove products for which a valid certificate/certification from Berlin Cert GmbH exists from the market for inspection. If deviations from the approved sample or defects are found during the inspection, the customer will receive written notification of the result of

the inspection and must bear all costs incurred by any necessary re-inspections. The contractual partner shall bear the costs of all expenses incurred in this connection.

§ 8 Contract term

These testing conditions shall come into force upon the first written order being placed by the contractual partner. The contract may be terminated by the contractual partner in accordance with the terms and conditions of business and contract. It shall also end if certification in accordance with § 3 cannot be successfully completed or if a certificate in accordance with § 6 must be withdrawn and the client does not hold any further certificates or has not submitted any further applications for certification.

§ 9 Termination

(1) Termination by the contracting party

Termination by the contracting party can be declared to Berlin Cert in writing without giving reasons.

(2) Notice period

The contracting party may terminate the contract at any time. At this point in time, the certificates will be revoked in accordance with § 6 .

(3) Termination for good cause

Both parties may terminate the contract for good cause without notice. Good cause shall be deemed to exist for the terminating contracting party in particular if the other contracting party violates essential provisions of the contract and has not remedied this within a reasonable period of time after receiving a warning about the breach of contract. Good cause shall be deemed to exist in particular if documents are not delivered in full or on time in the case of time-critical audits and after a request has been made with a deadline (see also § 4).

(4) Billing for services

In the event of termination, Berlin Cert will invoice for services already rendered on a pro rata basis in accordance with the Specific Terms and Conditions, as well as any additional costs incurred as a result of the termination.

§ 10 Complaints/Appeals Committee

In the event of disputes regarding the issuance, withdrawal, or suspension of certificates, as well as the certification process, the parties shall submit the dispute to the Berlin Cert Appeals Committee for a decision before taking legal action. The rules of procedure for the appeals/objections process shall apply.

The decisions of the Appeals/Objections Committee shall be binding on Berlin Cert. For the duration of the arbitration proceedings until a decision is made by the Appeals/Objections Committee or any subsequent court proceedings, the contested decision of the certification body shall remain in force.

§ 11 Final provisions

Amendments or additions to these terms and conditions must be made in writing. This also applies to the waiver of the written form requirement.

Should individual provisions of this agreement, including its components, be or become invalid, this shall not affect the validity of the remainder of the contract. In such a case, the parties shall replace the invalid provision with one that comes closest to the meaning and purpose of this contract in a legally permissible manner.

§ 12 Specific provisions

The regulations listed here apply in addition to the above points of the examination regulations for the respective certification procedure. They refer to the respective paragraph.

Management system certification according to ISO 17021-1

(1) It must not be implied, even tacitly, that the certification applies to activities or products that fall outside the described scope of certification. Use for unmentioned areas is expressly prohibited.

(2) The contractual partner is obliged to refrain from any reference to a system certification that could even implicitly suggest that the certification body has certified a product (including a service) or a process. This also applies to use on products, product packaging or accompanying information and any other manner that could be interpreted as a mark of product conformity.

(3) Certificates in accordance with EN ISO 13485 are reported every six months to the Central Authority of the German States for Health Protection in Medicines and Medical Devices (ZLG).

Conformity assessments in accordance with Regulation (EU) 2017/745

(1) Berlin Cert reports the issuance, renewal, restoration, withdrawal, suspension, refusal, restriction, and termination of certificates/attestations in accordance with the MDR to the EUDAMED electronic system.

(2) Berlin Cert enters all information on issued certificates into EUDAMED, including any changes and additions, as well as information on suspended, reactivated, or revoked certificates, cases in which the issuance of a certificate was refused, and restrictions on certificates. This information is available to the public.

(3) The contractual partner shall inform the certification body/notified body in writing of any changes and planned changes that are relevant to the system or product in terms of QM and/or QS requirements.