§ 1 Certification of quality management and quality assurance systems

Berlin Cert GmbH certifies quality management systems according to DIN EN ISO 13485 and DIN EN ISO 9001 as well as quality assurance systems according to Annexes IX and XI-a of the MDR. The submission of documents and further correspondence is permitted in German and English.

The Certification Body / Notified Body of Berlin Cert evaluates the documents submitted by your auditors and product reviewers. It decides on the award, termination, withdrawal, suspension, refusal, renewal, restoration and restriction of certificates.

The certification procedure is divided into the following phases:

1. submit the information necessary for the planning of the certification process, e.g. by completing the questionnaire on system certification including the annex „product".
2. preparing an offer
3. confirmation of the offer by the customer, consisting of the acceptance of the commercial offer and, also possible separately, the signing of the application (including submission of all necessary documents for the application review)
4. examination of the application, if neccessary notification to EUDAMED preparation of the contract in preparation for the certification procedure
5. confirmation of the contract and presentation of the conformity assessment team
6. review of technical documentation and clinical evaluation
7. joint audit planning and coordination
8. preliminary evaluation of the QM documentation
9. certification audit in the company
10. preparation of a detailed audit report
11. if necessary, implementation of corrective measures
12. certificate of approval and contractual agreement on the use of the logo
13. surveillance audits
14. unannounced audits
15. recertification audit

§ 2 Procedure for the provision of services

(1) Preparation of the company for certification

The request of a person interested in certification can be made in the form of a web form (web request) of the completed short questionnaire (short questionnaire) or as an informal e-mail or phone call.

It is important to ensure that the documents are filled in as completely as possible so that the certification body/notified body receives an initial assessment of your company directly on receipt. It will be checked whether Berlin Cert has the scope and the necessary resources to carry out certification. An assessment of the classification of the individual products given in the short questionnaire is also carried out.

Berlin Cert will get back to you as soon as the request has been checked and, if necessary, ask for further information (sending the short questionnaire including the annex „product", which serves to collect all the necessary information for the preparation of a certification offer, unless it has already been sent in advance).

If the documents are complete and the service can be provided by Berlin Cert (in the scope of the designation, resources available, ...), a corresponding offer for certification will be prepared. This will be approved by the head of the certification body and sent to you by e-mail together with the valid General Terms and Conditions and the certification regulations.

Berlin Cert offers the following services independent of the certification procedure:

a) Information discussion

Upon request, Berlin Cert will conduct an information meeting with the customer interested in certification before placing the order. Among other things, the following points can be discussed:

- Goal, benefits and requirements for certification;
- Procedure of the certification procedure;
- Standard basis, verification level, scope of application;
- Estimated costs;
- Date expectations of the customer.

The services listed in the following certification phases can be commissioned by the customer.

The information interview does not include information that could be construed as advice on the implementation or design of a QMS, products, product developments, documents or services.

(2) The certification process

After complete acceptance of the offer, consisting of acceptance of the commercial offer and signing of the application, an official application is created. This is followed by an application review, which includes checking the completeness and correctness of the documents submitted within a specified period by the customer (QM documentation, complete technical documentation including clinical evaluation). If the documents are incomplete or of insufficient quality, the application may be rejected. It will be decided on a case-by-case basis whether subsequent submission/correction of documents appears to be appropriate. If this is the case, up to three opportunities for rectification are granted. A review that is still negative after three rework opportunities as well as a rejection of an application generally results in a report to EUDAMED.

If all documents are complete, the customer will receive a confirmation from Berlin Cert and a template for a contract for certification. The customer sends the signed contract back to Berlin Cert. This is followed by the detailed design of the evaluation program, in which Berlin Cert names the intended audit team or lead auditor in the so-called audit team agreement. The client can reject an auditor or the team. For procedures under the MDR, however, the rejection of an auditor or product inspector must be justified. The Berlin Cert ensures that the regulations in standards and regulations concerning improper consulting activities by auditors are observed.

(3) Examination of technical documentation (TD) including clinical evaluation (KB/CER) - only for procedures according to MDR, not for certifications according exclusively to DIN EN ISO 13485.

For your product range, according to EU regulation 2017/745 ("MDR"). All your technical documentation must be reviewed in a five-year cycle.

Products are sampled according to MDCG 2019-13:

For Class IIa products, at least one Technical Documentation for each "category of devices" (i.e. products of an essentially common intended use or technology) is assessed in the initial certification process. This means the MDR-scopes as defined in EU regulation 2017/2185. The same applies to products in classes Ir and Im.

For Class IIb products, a representative technical documentation for each generic product group (i.e. products that have the same or a similar intended purpose, common technology or both) must be evaluated as part of the initial certification. This means the 4th level of the EMDN-System.

Sampling must include all products during validity Certification (see MDR, Annex VII, 4.5.2, indent 4).

All Class III products must be TD-tested before inclusion on a certificate.Sampling must include all products during validity Certification (see MDR, Annex VII, 4.5.2, indent 4). The sampling is meant „per certificate“.

The documents are checked "off-site". The investigator and any additional external clinical personnel called in will be sent to you for approval before the trial begins.

(4) Review and evaluation of documentation (audit stage 1, part 1)

The valid documents provided by the customer (e.g. the quality management manual and any other applicable documents such as process, work and test instructions) are checked by the

commissioned auditors for compliance with the requirements of the applicable standard and/or MDR.

(5) Certification audit in the company (audit stage 1, part 2; audit stage 2)

The certification audit is usually carried out by two auditors (lead auditor, technical auditor/product reviewer), but at least one lead auditor. If specific technical problems have to be solved, an appropriately qualified expert can be called in.

If the customer has outsourced important processes or procedures (in particular design development, production, testing) to external suppliers or subcontractors, an audit of these processes directly at the supplier or subcontractor can be part of the certification audit.

The customer receives the audit plan in good time before the start of the audit, which is agreed with him. As part of the company audit, the auditors check the effectiveness of the implemented system. The basis for this is the verification level of the agreed standard and EU Regulation 2017/745. The requirements of this standard are a guideline for the auditors, but do not prevent them from carrying out further surveys and investigations. The task of the auditors is to check the practical implementation of the documented procedures with regard to compliance with the requirements. The customer grants the auditors access to the relevant positions in the company and insight into the relevant records. He ensures that this also applies to his critical suppliers and subcontractors.

After completion of the audit, the customer is informed about the result of the certification audit in a final meeting. If deviations from the requirements are found in the course of the audit, these are stated in deviation reports. The deviations are explained on the basis of the available deviation reports and deadlines are set for the completion of corrective actions or for the submission of an action plan. The reports must be countersigned by the customer's audit representative.

If a post-audit is required, the date shall be set. The documentation of the post-audit is carried out analogously to the certification audit.

Finally, the customer receives a detailed audit report with the evaluation by the auditors. If, during a certification audit, such serious deviations become apparent that the auditors are unable to recommend the issue of the Berlin Cert certificate, the audited company must be informed of the termination of the certification audit.

In the event that the audit is cancelled on site, at least the day started will be charged in full for all auditors.

(6) Issuance of certificates, surveillance audit and unannounced audit

(a) issue of certificates

The certification body issues a certificate if all provisions of the relevant standard or EU Regulation 2017/745 are fulfilled. The validity period of DIN EN ISO 13485 certificates is a maximum of 3 years, that of conformity certificates according to Annex IX and XI-a of the MDR a maximum of 5 years if annual surveillance audits are carried out in the company with positive results. In special justified cases, an additional audit can be carried out at the customer's expense. The valid certification will be made known to the public in an appropriate manner. This is done with a current list of certificates made available on request or on the Internet.

(b) Surveillance audits

Within the scope of the surveillance audits, the internal audits and changes in the system and, if applicable, the products as well as randomly selected elements of the system are checked in particular.

If the customer has outsourced important processes or procedures to external suppliers or subcontractors (in particular design development, production, testing), an audit of these processes directly at the supplier or subcontractor can be part of the monitoring audit.

In particular, the audit report and the corresponding deviation reports of the available audits form the basis. The date for the surveillance audit takes place within a period of 12 months after the preceding audit. Deviations shall be dealt with in accordance with the certification audit procedures.

The customer receives a report on the surveillance audit.

If the certification requirements change, e.g. due to a revision of the underlying standard or regulation or due to changes in the certification regulations, the certification body/notified body will inform the customer of the changes and agree an appropriate transition period for the resulting measures.

(c) Unnounced audits

In the case of conformity assessments according to MDR, in addition to the surveillance audits, unannounced audits shall be carried out at least once every five years at the premises of the customer or its major suppliers or subcontractors.

In the course of the unannounced on-site audits, a product/products is/are removed from ongoing production and checked for compliance with the specifications of the underlying technical documentation and the basic requirements on the basis of the available evidence of production and the materials used, as well as the traceability of all critical components and materials.

Should it not be possible to assess compliance with the Essential Requirements on this basis, additional necessary tests will be arranged or carried out by Berlin Cert GmbH. The products to be tested are made available to the Notified Body free of charge for this purpose. Alternatively, the Notified Body may also purchase a product on the market and subsequently invoice the customer for the purchase price.

Within the scope of the unannounced on-site audits, a more detailed examination of at least two critical work processes, such as design control, preparation of material specifications, purchase and control of incoming material or components, assembly, batch release, packaging and quality control of the product, takes place.

Independent of the above described non-event related unannounced audits, non-event related unannounced audits can also be carried out for procedures according to DIN EN ISO 13485.

(d) Recertification audits

Before the validity period expires, a recertification audit must be carried out in the company to extend the validity of the certificate for a further cycle. The recertification audit checks the effectiveness of the entire quality management system.

§ 3 General terms and conditions

(1) Duties and responsibilities of the customer

By signing the contract, the customer declares his willingness to certify the system,

1. not to have submitted to any other certification body a parallel application for certification related to the designated products and systems or information on any previous applications for the same quality management system for that product

2. fulfil the obligations arising out of the approved quality management system;

3. maintain the approved quality system so as to ensure that it remains adequate and effective;

4. that employees or representatives of accreditation bodies and designating authorities may participate in the audit to verify the competence of the audit team within the framework of so-called "observed audits". He shall ensure that this also applies to his subcontractors;

5. grant auditors and product reviewers access to all areas and to all documents and records, as necessary for the assessments commissioned;

6. establish and maintain a systematic procedure to record and evaluate experience with products and services at the post-production stage and to make arrangements to make any necessary corrections;

7. inform the competent authorities and the certification/registration body/notified body immediately upon becoming aware of any of the following occurrences:

i. all notifiable occurrences must - according to Art. 87 of the MDR - be reported immediately in writing to Berlin Cert and reported to EUDAMED according to Art. 92 of the MDR

ii. any malfunction or change in the characteristics and/or performance and any inadequacy in the labelling or instructions for use of a product which may lead or has led to the death or serious deterioration of the health of a patient or user;

iii. any technical or medical reason related to the characteristics and performance of the product for the reasons referred to in (i) and which has led to the systematic recall by the manufacturer of products of the same type;

8. provide the certification/registration body with full documentation of the quality management system to be assessed and the necessary product documentation (evidence of compliance with the general safety and performance requirements); as well as documentation of the manufacturer's post-market surveillance system and, where appropriate, the clinical follow-up plan and procedures to ensure compliance with the obligations arising from the vigilance provisions referred to in Articles 87 to 92 of the MDR;

9. provide the certification body/notified body with information on outsourced processes, key suppliers and subcontractors and use of management system consulting services;

10. in the case of conformity assessments in accordance with MDR, ensure that auditors and product reviewers have access at all times to all relevant areas and to all relevant documents and records of the customer as well as of important suppliers and subcontractors concerning outsourced processes and activities for the customer. If the customer or a supplier or subcontractor operates in a country for which German citizens require a visa, the customer shall ensure that the auditors and product reviewers can enter that country at any time and without prior notice for the purpose of conducting unannounced audits (e.g. by inviting the supplier or subcontractor to do so, with the date of the visit and the date of signing kept open);

11. in the case of conformity assessments under MDR, to keep the Notified Body informed of periods during which individual products covered by the Notified Body certificate are not produced;

12. inform the notified body in writing of any changes and planned changes that are relevant to the system or product in terms of the QM and/or QS requirements. These could be e.g. changes concerning:

i. the certified quality management or quality assurance system;

ii. legal status, economic status or ownership;

iii. Changes in company structure and organisation;

iv. key personnel, organisation and management;

v. contact addresses, locations and critical suppliers;

vi. the scope of the activities covered by the certified management system;

vii. the product portfolio and technical data of the products (technical design, intended use, significant changes in risk management or clinical evaluation, etc.).

13. to inform Berlin Cert prior to awarding the contract about comparable audits that have already been carried out by other bodies on the same system;

14. to provide Berlin Cert with the valid documents before each monitoring and recertification audit and to list the changes made;

15. to use the provided certification marks only within the scope of the certified scope of application, in particular not erroneously in connection with the advertising of products and product packaging;

16. to implement necessary measures resulting from changes to the certification regulations within a reasonable period of time;

17. to implement necessary measures resulting from changes in the underlying standards, statutory regulations and ordinances within the respective transition periods;

18. to use the marks provided by the certification body in the form of files or print templates only in such a way as to make the status of the customer as a certified company in accordance with DIN EN ISO 13485 externally recognisable.

The customer declares to the certification body that:

i. he does not use these mark(s) on products or product packaging which can be seen by the consumer or used in any other way which could be interpreted as marking for product conformity,

ii. it does not apply these mark(s) to laboratory test reports, calibration certificates, inspection reports or certificates,

iii. it does not provide misleading information about its certification status,

iv. in the event of suspension or withdrawal of its certification in accordance with the instructions of the certification/registration body, it ceases to use any promotional material containing references to the certification/registration status,

v. amend any promotional material within a reasonable time when the scope of certification has been reduced,

vi. it does not allow any reference to its management system certification that could imply that the certification/registration body is certifying a product (including a service) or process,

vii. it does not imply tacitly that the certification applies to activities outside the scope of the certification.

viii. it does not use the certification in a manner that discredits the certification body and/or certification system or leads to a loss of public confidence.

	Completed process	Deadline D= Desired and L=Latest	Responsibility Assistance	Remark
Deadlines, which must be met by the applicant / certified customer				
III.1	Provision of technical documentation (if applicable)	- for EZ/RZ transfer: With submission of the application - to the regular inspection: On request	QMB from applicant or certified person	No audit can take place before a complete evaluation (incl. report, with development cooperation with positive evaluation and with development cooperation with new customers). A certificate can only be issued after a successful audit and positively evaluated technical documentation (for EZ and RZ new customers)!
III.2	Confirmation of the inspector of the technical	14 days after delivery	QMB from applicant or certified person	After expiry of the deadline, tacit consent will be assumed.
III.3	Provision of QM documentation in stage 1 Audit	Upon submission of the application	QMB from applicant or certified person	No audit stage 2 can take place prior to testing!
III.4	Returning the FB 299	3 months (W) 6 weeks (S) before the audit date	QMB from applicant or certified person	If there have been major changes in the company, it may be necessary to recalculate the audit time. Therefore: If the audit is sent later, the audit date may be postponed!
III.5	Confirmation of the audit team	1 day (W) 5 days (S) after sending the audit team agreement	QMB from applicant or certified person	No audit can take place before written confirmation!
III.6	**Closing** of minor and major deviations (also applies to post-audits) For TD/CEAR no subdivision: here only deviations (AB)	60 days (W) 90 days (S) after the last day of the audit or receipt of the test report (not after the post-audit!)	QMB from applicant or certified person	Ensuring the functionality of the QM/QS system. After expiry of this period, the certificate/certificate may

	Completed process	Deadline D= Desired and L=Latest	Responsibility Assistance	Remark
				be suspended!
III.7	Feedback after sending of audit report	14 days after delivery	QMB from applicant or certified person	After expiry of the deadline, tacit consent will be assumed.

(2) Duties and responsibilities of the certification body / notified body

The certification body / notified body undertakes to accept the certification,

1. to provide the customer with a certification mark corresponding to the scope of certification in the form of a suitable electronic template for the period of validity of the certificate;
2. to inform the customer about relevant changes to the underlying standards and norms as well as the present certification regulations;
3. that, as the appointed certifier, it bears the overall responsibility for the order, even if orders are placed with external experts as part of the certification process;
4. to ensure the professional competence of the commissioned product reviewers as audit team leaders (hereinafter also referred to as lead auditors) and auditors;
5. to ensure confidentiality vis-à-vis third parties, impartiality, independence and freedom from conflicts of interest of all internal and external employees engaged in the certification procedure;
6. if subcontractors assume tasks, Berlin Cert GmbH shall inform the customer of this assignment. Berlin Cert GmbH ensures that the points described under 5 also apply to the subcontractor.
7. that the customer is entitled to reject any product reviewer and audit team member in case of doubt about the essential characteristics mentioned under point 4 and point 5 without stating further reasons;
8. to provide the customer with all documents necessary for the assessment of the aspects mentioned under points 4 and 5.

§ 4 Termination, Withdrawal, Suspension, Refusal and Limitation of Certificates

A certificate or attestation loses its validity if, in particular:

1. the validity period has expired, unless the customer requests an extension at least three months before expiry and fulfils the associated conditions;
2. insolvency proceedings have been instituted against the customer or suspended for lack of assets.

The customer shall immediately report such incidents to Berlin Cert;

3. the customer's business operations are discontinued;
4. the legal or normative requirements or the rules of technology on which the certificate is based change, unless the customer proves within a set period of time by means of an inspection by Berlin Cert that the system complies with the new requirements/rules;
5. a product marked with a symbol of Berlin Cert GmbH or a CE marking with reference to a conformity certificate of Berlin Cert GmbH does not comply with the approved type.

A certificate may be terminated, withdrawn, suspended or restricted without notice if:

1. misleading or otherwise inadmissible advertising with the certificate is carried out or the certificate is missused or the certification is used in a form that discredits Berlin Cert;
2. legal regulations or official requirements are not or no longer complied with;
3. Berlin Cert determines that relevant requirements of EU regulations have not been fulfilled or are no longer fulfilled by the customer, or that a certificate or attestation should not have been issued;
4. defects in the system are detected; or essential requirements of the certified system are not or are no longer met;
5. a surveillance audit or the verification of product conformity cannot be carried out on time despite a written request or if deviations are not eliminated within the agreed period by appropriate corrective measures;
6. the customer refuses or does not permit the inspection of the production and testing facilities or the warehouse by the representative of Berlin Cert GmbH or the removal of products for inspection, and a proper performance of the production monitoring is not possible despite written request within a period specified by Berlin Cert GmbH;
7. an unannounced audit at the customer's or one of its important suppliers and subcontractors cannot be carried out or cannot be carried out successfully;
8. the customer does not settle claims of Berlin Cert despite a reminder. Even in the case of partial non-payment, all certificates can be cancelled;
9. the customer objects in writing to an amendment to the General Terms and Conditions or the Certification Regulations within 6 weeks of such amendment coming into effect or its possibility of becoming aware of it;
10. the customer violates the terms and conditions or the certification regulations of Berlin Cert, provided that this is not only due to slight negligence or is not an insignificant violation.

Before a certificate is cancelled, withdrawn, suspended, refused or restricted by Berlin Cert, Berlin Cert shall give the client the opportunity to be heard, unless such a hearing is not possible due to the urgency of the decision to be taken or the client has been notified in writing of the withdrawal of the certificate within a sufficient period of time (e.g. reminder for default of payment).

Further advertising or any other use of the certificate is not permitted in the aforementioned cases. If required by Berlin Cert, all certification documents must be returned. Fees already paid will not be refunded; unpaid fees must be paid in full. Berlin Cert shall not be liable for any disadvantages incurred by the customer as a result of non-issuance, termination, suspension, refusal, restriction, revocation or expiry of a certificate, except in cases of intent and gross negligence.

§ 5 Reporting obligations of the certification body/notified body

Berlin Cert notifies the electronic system EUDAMED of exhibitions, renewals, restorations, withdrawals, suspensions, refusals, restrictions and cancellations of certificates according to the MDR; certificates according to DIN EN ISO 13485 are reported to the supervisory authority ZLG every six months.

In EUDAMED, the BS enters all information on issued certificates, including their amendments and supplements, as well as information on suspended, reactivated or revoked certificates and on cases in which the issuance of a certificate has been refused, as well as on restrictions on certificates. This information shall be made available to the public.

Furthermore, Berlin Cert offers a certificate query for all issued certificates on its homepage in accordance with the requirements of DIN EN ISO/IEC 17021-1, which, however, only displays the content of the issued certificate and its validity status.

§ 6 Market control

Berlin Cert GmbH can withdraw products for which a valid certificate of Berlin Cert GmbH exists from the market at any time for control testing. If deviations from the approved sample or defects are found during the control inspection, the customer will receive a written notification of the result of the inspection and must bear all costs arising from any necessary follow-up inspections.

§ 7 Objection procedure

The customer may lodge a written objection against the decisions of Berlin Cert GmbH within the framework of the testing and certification procedures carried out. Berlin Cert GmbH will respond to the objections submitted within 4 weeks and forward them to the objector in writing. The objection process H6.2.2 of Berlin Cert GmbH regulates further details.

In all other respects, the General Terms and Conditions valid at the time shall apply.