§ 1 Certification of quality management and assurance systems

Berlin Cert GmbH certifies quality management systems in accordance with DIN EN ISO 13485 and DIN EN ISO 9001 (not accredited) as well as quality assurance systems in accordance with Annexes II, V, and VI of the Directive 93/42/EEC.

The certification authority/notified body of Berlin Cert evaluates the documents submitted by our auditors and technical experts. It makes a decision about awarding, terminating, withdrawing, suspending, refusing, renewal, restoring or limiting certificates.

The certification processes are divided into the following phases:

1. Submitting the necessary information for planning the certification process, e.g. by completing the system certification questionnaire.
2. Creating and confirming an offer
3. Preparing applications for the certification process
4. Confirming the application and introducing the audit team
5. Joint audit planning and organising
6. Preliminary evaluation of the QM documentation
7. Certification audit in the company
8. Creating a detailed audit report
9. If necessary, implementing corrective actions
10. Certificate issuing and contractual agreement for using the mark
11. Monitoring audits
12. Unannounced audits
13. Recertification audit

§ 2 A Procedure for managing the service

(1) Preparing the company for certification

Regardless of the certification process, Berlin Cert provides the following services:

a) Information session

On request, Berlin Cert holds an information session with customers interested in certification before performing the job. The following points discussed may include:

- The objective, benefits, and requirements of certification;
- Expiration of the certification process;
- Underlying standards, evidence, audit scope;
- Estimated costs;
- Potential deadlines for the customer.

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

(2) The certification process

After the customer accepts the offer, they receive a confirmation of it from Berlin Cert and a template for the request for certification. The customer fills out the application and sends it completed and signed to Berlin Cert. Berlin Cert will also designate the planned audit team and lead auditor in the audit team agreement. The customer has the right to refuse an auditor or the team. Berlin Cert will ensure that the regulations for standards and procedures on unacceptable consulting activities by auditors are complied with.

(3) Checking and evaluating the 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 procedures, work, and inspection instructions) are checked by the certifying auditors for compliance with the requirements of the relevant standards and/or policies.

(4) Certification audit in the company (Audit Stage 1, part 2; audit stage 2)

The certification audit is generally carried out by two auditors (lead auditor, specialist auditor/expert), or at the least by a lead auditor. If especially professionally specific problems must be solved, a suitably qualified expert may be consulted.

If the customer outsources important processes or procedures (esp. design development, manufacturing, testing) to external suppliers or subcontractors, an audit of these processes may be part of the certification audit directly from the supplier or subcontractor.

The customer receives the audit plan in good time before the start of the audit, which is agreed on with the customer. As part of the audit in the company, the auditors check the effectiveness of the implemented system. The basis is the verifying level of the agreed standard. The requirements of the agreed standard apply as a guide for the auditors, but does not stop them carrying out further inquiries and investigations. It is the auditors job to review the practical implementation of documented procedures with regard to meeting the requirements. The customer will provide auditors access to the relevant places in the company and access to the relevant records. Where necessary, the customer will ensure that this also applies to critical suppliers and subcontractors.

After completion of the audit, the customer is informed of the outcome of the certification audit in a final meeting. If deviations from the requirements are determined in the course of the audit, they will be named in an incident report. The deviations will be explained in the incident report and dates for completing the corrective actions or for submitting an action plan will be arranged. The reports are to be signed by the audit officer commissioned by the customer.

If a re-audit is required, the date will be arranged. The documentation of the re-audit is carried out in accordance with the certification audit. The cost of a re-audit or reviewing the corrective actions will depend on expenses and the current cost rates.

Finally, the customer will receive a detailed audit report with the evaluation by the auditors. If deviations are observed during the certification audit that are so serious that the auditors cannot recommend that Berlin Cert issues the certification, the audited company will be notified of the termination of the certification audit.

(5) Issuing certificates, monitoring audits, and unannounced audits

(a) Issuing certificates

The certifying authority issues a certificate if all requirements of the relevant standards and directives are met. The Berlin Cert Certificate according to DIN EN ISO 13485 is valid for a maximum of 3 years and certificates according to Annex II, V and VI for a maximum of 5 years, if surveillance audits are carried out in the company with positive results every year. In specially justified cases, an additional audit can be carried out at the expense of the customer. The valid certification is identified in an appropriate manner to the public. This can be done with a current certificate list provided upon request or on the Internet, for example.

(b) Monitoring audits

As part of the monitoring audits, in particular the internal audits and changes in the system and, if necessary, the products and randomly selected elements of the system are checked.

If the customer has outsourced important processes or procedures to external suppliers or subcontractors (esp. design development, manufacturing, testing), an audit of these processes may be part of the monitoring audit directly from the supplier or subcontractor.

The basis is in particular the audit report and the associated deviation reports of this audit. The date of the monitoring audit will be within a period of one year after the preceding audit ± 90 days. Deviations are handled in accordance with the procedures in the certification audit.

The customer receives a report of the monitoring audit.

If the requirements for certification change, e.g. due to a new version of the underlying standards or guidelines or due to changes in the certification regulations, the certification body/notified body will inform the customer of these changes and agree on an appropriate transitional period for the measures resulting from this.

(c) Unannounced audits

In the case of a conformity assessment in accordance with Directive 93/42/EEC, in addition to the monitoring audit at least once every five years unannounced audits will be carried out on the customer or their key suppliers or subcontractors.

As part of the unannounced audits on site, a product/products will be taken from the current production and checked with reference to the available evidence regarding the manufacture and the materials used in accordance with the requirements of the underlying technical documentation and the basic requirements, as well as the traceability of all critical components and materials.

If the assessment of conformity with the essential requirements on this basis is not possible, additional required tests will be initiated or performed by Berlin Cert GmbH. The products to be tested are provided to the notified body for this purpose free of charge. Alternatively, the notified body can also buy a product on the market and then invoice the customer for the purchase price.

As part of the unannounced audit on site, a more detailed check is performed of at least two critical workflows such as design control, preparing material specifications, purchasing and control of incoming materials or components, assembly, sterilisation, batch release, packaging, and quality control of the product.

Event driven unannounced audits may be performed on procedures based on DIN EN ISO 13485, too.

(6) Recertification

Before the certificate expires, a recertification audit will be carried out at the company to extend the validity of the certificate for another cycle. During the recertification audit, the effectiveness of the entire quality management system is reviewed.

§ 3 General conditions

(1) Obligations and responsibility of the customer

By signing the application for the system certification, the customer agrees

1. to not have submitted a parallel application for certification with any other certification body regarding the specified products and systems;
2. to meet the obligations arising from the approved quality management system;
3. to maintain the approved quality management system in such a way that its suitability and effectiveness remains;
4. that employees or representatives of accreditation bodies and designating authorities can take part in the audit to examine the competence of the audit team as part of observed audits. The customer ensures that this also applies to their subcontractors;
5. that the auditors and technical experts are granted access to all areas and all documents and records;
6. to set up and maintain a systematic procedure with which the experience with products and services in the post-production phase is recorded and evaluated, and to fulfill the provisions to carry out the necessary corrections;
7. to inform the competent authorities and the certification body/notified body without delay of the following incidents as soon as they are aware of them:
    i. Berlin Cert is to be notified immediately in writing of all reportable incidents according to §29 of MPG
    ii. Any malfunction or deterioration in the features and/or performance and any inaccuracies in the labeling or the instructions for use of a product which may lead or has led to death or a serious deterioration in the health of a patient or user;
    iii. Any type of technical or medical reason which is caused due to the specified causes in clause i) through the features and performance of the product and led to the systematic recall of the same type of products by the manufacturer;
8. To provide the certificating authority with the full documentation of the quality management system to be evaluated and the necessary product documents (proof of compliance with the essential requirements) (transfer or inspection);
9. To provide the certification authority /notified body with the information on outsourced processes,key suppliers and subcontractors, and the use of advisory services relating to the management system;
10. In the case of a conformity assessment in accordance with Directive 93/42/EEC, to ensure that the auditors and technical experts have access at all times to all relevant areas and documents and customer records as well as the key suppliers and subcontractors concerning outsourced processes and activities for the customer. If the customer or a supplier or subcontractor is working in a country where German citizens require a visa, the customer shall ensure that the auditors and technical experts are allowed to enter this country for the purpose of carrying out unannounced audits at any time and without notice (e.g. through a referral of the supplier or subcontractor, in which the date of the visit and the date of signature are kept open);
11. In the case of a conformity assessment in accordance with Directive 93/42/EEC, the notified body must be notified regularly over a period of time in which individual products are not produced relating to the certificate from the notified body;

12. The commissioned certification authority must be informed in writing of changes and planned changes that are relevant as defined by the QM and/or QS requirements system or product. For example, these could be changes with regard to:
    i. The certified quality management or assurance system;
    ii. The legal status, economic status, or ownership;
    iii. Changes in the company structure and organisation;
    iv. Key personnel, the organisation and management;
    v. The contacts, locations and critical suppliers;
    vi. The scope of activities under the certified management system;
    vii. The product portfolio and technical data of the products (technical structure, purpose, significant changes in risk management or clinical evaluation, etc.).

13. To inform Berlin Cert of similar audits before awarding the contract that have been performed by other authorities on the same system;
14. To provide Berlin Cert before every monitoring and recertification audit with valid documents and list the changes made;
15. To only use the certification label provided as part of the certified scope, in particular to not wrongly use it in connection with promoting products and product packaging;
16. To implement the necessary actions arising from changes in the certification regulations or the underlying standards in a timely manner;
17. To use the certification labels, provided by the Berlin Cert in terms of data or printer´s copies, only for external identification as a certified organization after the DIN EN ISO 13485.
18. Any fees (including daily rates, travel expenses, cancellation of appointments, creation of new certificates, termination, etc.) can be found in the fee list which is sent together with the offer. In addition, it is also available on the website of Berlin cert (www.berlincert.de).

The customer agrees to:

i. not use these labels on products or packaging of products, which can be seen by the user or not use them in any way which can be interpreted as an identification of product conformity.

ii. not to apply the logo(s) to laboratory test, calibration or inspection reports or certificates,

iii. not give misleading information about their certification status.

iv. end the usage of all advertising material which hold references of the certification status, if it comes to termination, withdrawal, suspension, refusing or limitation of certification according to the directive of the certification authority.

v. change all advertising material, if the scope of the certification will be reduced.

vi. not allows any reference to their management system certification, which may imply that the certification authority certifies a product (including a service) or a process.

vii. not implies that the certification counts for operations or locations which are out of scope of the certification

viii. not to use the certification in any way that can discredit the certification authority and/or the certification system or lead to the loss of the public trust.

Deadlines, which must be met by the applicant / certified customer				
Nr.	**Completed process**	**Deadline D= Desired and L=Latest**	**Responsibility Assistance**	**Remark**
III.1	Provision of the technical documentation (only guideline processes)	6 month (D) 3 month (L) before the audit date	Quality Manager of the applicant / certified customer	Prior to a complete evaluation (incl. report) no audit can take place!
III.2	Confirmation of the auditor of the technical documentation	14 days after reconsignment	Quality Manager of the applicant / certified customer	After expiration of the deadline approval will be implied
III.3	Provision of the QM-documentation in the stage 1 audit	8 weeks (D) 4 weeks (L) before the audit date	Quality Manager of the applicant / certified customer	Prior to an evaluation no audit can take place!
III.4	Reconsignment of the FB_299	3 month (D) 6 weeks (L) before the audit date	Quality Manager of the applicant / certified customer	With delated reconsignment the audit date may be rescheduled!
III.5	Confirmation of the audit team	1 day (D) 5 days (L) after sending the audit team agreement	Quality Manager of the applicant / certified customer	Without the written confirmation the audit cannot take place!
III.6	**Closing** of minor- and major deviations (same applies for re-audits)	60 days (D) 90 days (L) after the last day of the audit (not after the re-audit!!)	QQuality Manager of the applicant / certified customer	After expiration of the deadline certificates may be suspended!
III.7	Feedback after sending of the audit report	14 days after reconsignment	Quality Manager of the applicant / certified customer	After expiration of the deadline approval will be implied

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

By accepting certification, the certification authority/notified body is obligated

1. To give the customer a certifying label for the period of validity of the certificate in the form of a suitable electronic copy;
2. To inform the customer of relevant changes to the underlying standards and norms and the present certification regulations;
3. As a delegated certifying body, they also bear overall responsibility, for awarding contracts in the context of certification of external experts;
4. To ensure the expertise of the experts appointed as audit team leaders (referred to below as lead auditor) and auditors;
5. To ensure confidentiality from third parties, the impartiality, independence, and freedom from conflicts of interest of all internal and external staff in the certification process ;
6. To ensure that the customer is entitled to reject any professional expert or audit team member if they are in doubt as to essential characteristics specified under point 4 and 5, without giving further reasons;
7. To provide the customer with all documents necessary for the assessment referred to in points 4 and 5.

§ 4 Termination, withdrawal, suspension, refusing and limitation of certificates

A certificate or approval/license loses its validity if, in particular:

1. The validity period has expired, unless the customer applies for an extension at least three months before it expires and meets the necessary conditions;
2. If insolvency proceedings against the customer begin or there is a lack of assets.
   The customer must immediately notify Berlin Cert of such occurrences;
3. That changes the customer's business;
4. If the legal or normative requirements or regulations of the technology change that the certificate is based on, unless the customer proves via a subsequent check by Berlin Cert within a certain period that the system complies with the new requirements/rules;
5. A product marked with a label by Berlin Cert GmbH or a CE label with reference to a certificate of conformity from Berlin Cert GmbH does not match the approved type.

A certificate may be terminated, withdrawn, suspended, or restricted without reference to the notice period if:

1. Misleading or unauthorized advertising is used with the certificate or the certificate is misused, or certification is used in a way which brings Berlin Cert into disrepute;
2. Statutory provisions or official requirements are no longer met;
3. Berlin Cert finds that relevant requirements of EC Directives have not been met by the customer or are no longer met, or a certificate or approval should not have been issued;
4. Defects in the system are found;
5. A monitoring audit or verification of product conformity cannot be carried out despite a written request within 4 weeks or if deviations are not eliminated within the agreed period through appropriate corrective actions;
6. The customer refuses or does not allow the representative of Berlin Cert GmbH to inspect the production, testing, or warehouse or to withdraw products for review, and proper implementation of production monitoring is not possible despite a written request within a period specified by Berlin Cert GmbH;
7. An unannounced audit of the customer or one of its major suppliers or subcontractors cannot or not successfully be carried out;
8. Essential requirements of the certified system are no longer fulfilled;
9. The customer does not pay Berlin Cert despite reminders. Even if partial payments are made, all certificates can be terminated;
10. The customer objects in writing to a change in the Terms and Conditions or the certification within 6 weeks after they come into force or they are informed of them;
11. The customer violates the Terms and Conditions or the certification of Berlin Cert, if this is not only due to slight negligence or it is not a significant violation.

Before a certificate is terminated, withdrawn, suspended, refused or restricted by Berlin Cert, Berlin Cert gives the customer the option of a hearing, unless such a hearing is not possible in view of the urgency of the decision to be taken or the suspension of the customer's certificate was announced in writing (e.g. warning for late payment) with a sufficient notice period.

If the reasons for the suspension of (product) certificates are not rectified or not clarified, they will be withdrawn after a period of 3 months.

Other advertising or any other use of the certificate is prohibited in the specified cases. If demanded by Berlin Cert, all certification documents must be returned. Fees already paid will not be refunded; unpaid fees are payable in full. Berlin Cert is not liable for disadvantages arising to the customer from non-issue, termination, suspension, refusing, limitation, withdrawal, or lapse of a certificate, except in cases of willful misconduct and gross negligence.

§5 report obligations of Berlin Cert

Issuing, renewal, restoring, withdrawal, suspension, refusing, limitation or termination of certificates pursuant to the Annexes of Directive 93/42/EEC are reported to the *German Institute for Medical Documentation and Information* (DIMDI); certificates in accordance with DIN EN ISO 13485 are biannually reported to the ZLG Authority.

Berlin Cert GmbH is also obliged to notify DIMDI of "negative" certificates in cases where certification or monitoring in accordance with Directive 93/42/EEC could not be successfully completed in the given time frame (e.g. due to non-submission or non-timely submission of evidence of remedy in nonconformities). The same applies to attempts at deception.

Furthermore, Berlin Cert offers according to the requirements of the DIN EN ISO/IEC 17021-1 a certificate status retrieval function for all issued certificates on its homepage. Data shown by this function is limited to the content of the offered certificates at maximum. Furthermore, the status of validity is shown.

§ 6 Market control

Berlin Cert GmbH may at any time remove products from the market which have a valid certificate from Berlin Cert GmbH to inspect them. If the inspection finds deviations from the approved sample or deficiencies, the customer will receive a written notice of the result of the inspection and must bear all the costs incurred resulting from the required subsequent inspections.

§ 7 Opposition procedure

The customer can submit a written objection against the decisions of Berlin Cert GmbH as part of the testing and certification procedures carried out. Berlin Cert GmbH will take a stance on the objections put forward within 4 weeks and send it to the objector in writing. The details are governed by the opposition process H6.2.2 of Berlin Cert GmbH.

Moreover, the current version of the general Terms and Conditions apply.

Please note, that only the german version of this document (MU_002) is legally valid. This translation is for information purposes only and not legally binding. You can find the german version on our homepage.