

MU_005_Audit and certification process

This document covers procedures for

certification body

- Quality management systems according to EN ISO 13485

Notified Body

- Conformity assessments according to Regulation (EU) 2017/745, MDR

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Note: Berlin Cert is, among other things, an accredited certification body and notified body. For the sake of readability, the general term "certification body" is used in this document.

Governing Language

The original version of these Terms and Conditions 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 Principles of Berlin Cert certification

Certification of an organization begins with a two-stage initial audit and includes one review in each of the following two years.

As part of the MDR procedure, one review is carried out in each of the four subsequent years and at least one unannounced audit per validity period of the certificate of conformity, which is a maximum of five years.

Recertification marks the start of a new certification cycle, which is structured in the same way as the initial certification with regard to verification and surveillance audits.

The surveillance audits can be used to determine the extent to which the organization and its management system have improved. In addition, the auditors work with the organization to identify potential improvements in the management system and system performance. Only auditors with a high level of technical and methodological qualifications are used for this purpose.

The audit team:

- reviews the management system and verifies compliance with the organization's internal procedures,
- determines whether the processes and procedures have been effectively introduced, implemented, and maintained, and whether the objectives and targets are being pursued,
- checks compliance with normative requirements.

If the organization operates at several locations, audits are also carried out at the locations during the certification cycle. In the case of MDR procedures, this also applies to critical suppliers; in the case of procedures according to DIN EN ISO 13485, this may also apply to outsourced processes.

Special features of the Berlin Cert certification procedure:

- Individual support for the organization in preparing for and implementing the procedure, as well as rapid response to inquiries.
- An organization is seen as a partner. The aim of the audits is to improve the organization's business processes in the long term.
- Standards are a collection of expert knowledge. Berlin Cert auditors apply them only after taking into account the individual circumstances of each customer.
- Berlin Cert employees have a high level of skills and technical expertise to implement these principles.

The individual processing of offers, the good preparation of the auditors in order to make effective use of the time during the on-site audit, and the constant personal availability of the auditors and employees in the certification body are important prerequisites for achieving these goals.

2 Initial certification

2.1 Preparation for the two-stage initial audit

Data collection

When an organization contacts Berlin Cert, it is sent a form for initial data collection, with a request to provide some basic information. To speed up the process, this data collection can also be done by telephone or online.

Preparation of an offer

Based on the basic data, Berlin Cert prepares a quotation describing the costs and conditions for certification or conformity assessment. In addition, a first draft of the audit program is presented, which takes into account the size of the organization, the scope and complexity of the management system, the products and processes, as well as the stated level of effectiveness of the management system and

the results of previous audits. In the interest of the organization, all possibilities for reducing the audit time are utilized and, if necessary, remote audits are also planned.

If the organization confirms the offer or places an order on this basis, a desired date for the audit can already be specified.

For all procedures in accordance with EN ISO 13485 (DAkKS), Berlin Cert can review the offer on the basis of the Level 1 audit report and modify it if necessary.

Conclusion of contract and application

Once the order has been placed, Berlin Cert compiles all relevant data (address details, other locations, scope, contact persons, authorized representatives, etc.) of your company into a formal application, which you must then review, comment on, sign, and return to Berlin Cert. If there are any relevant changes to the initial data collection, the audit program and, if necessary, the audit costs will be adjusted in consultation with you.

Conclusion of contract, selection of auditors, technical experts, and other participants

After successful review and approval of the certification application, including the final audit program, Berlin Cert will put together an audit team. The client has the opportunity to cite reasons against the appointment of an auditor. These reasons must be communicated to Berlin Cert immediately after the auditor's name has been announced. In such cases, Berlin Cert will examine whether the reasons given are sufficient to change the auditor and will inform the client of this decision. When appointing a replacement auditor, Berlin Cert will take particular care with regard to the reasons given by the client.

To better prepare for the certification process, the Berlin Cert audit checklist is made available to the organization. The audit leader prepares a detailed audit plan.

The auditors are appointed based on their technical expertise in the respective industries and are regularly trained on current issues relating to the relevant management systems and international standards. Both auditors and experts (product auditors, clinicians, technical experts) are subject to strict neutrality and, for this reason, are not permitted to provide or have provided consulting services to the respective organization for three years prior to and after certification.

The term "consulting" covers participation in the development, implementation, or maintenance of a management system or the design of technical documentation. This also includes the performance

of internal audits. Training courses and seminars also fall under the term "consulting" if company-specific solutions are offered. Auditors are obliged to maintain absolute confidentiality regarding the information they receive in the course of their work.

Furthermore, technical experts, interpreters, and translators may be used to support the auditors with specific knowledge or expertise in the activity being audited, in the language, or in the culture, thereby enabling effective oral or written communication. These persons are subject to the guidance of the lead auditor and must be selected and deployed in such a way that they do not exert undue influence on the audit.

2.2 Certification procedure / conformity assessment procedure

The initial certification audit is carried out in two stages:

Stage 1 audit

The Stage 1 audit always includes a review of the management system documentation. The organization receives a detailed list of the minimum documents to be submitted.

The document review begins approximately 6 weeks before the target audit date. By this time, the organization's management documentation and approval of the auditors proposed by Berlin Cert should be available. The management system documentation normally includes the management manual and the procedural instructions. Additional documents, such as work instructions or forms, which are necessary for understanding the entire system, should also be submitted.

The Level 1 audit serves to assess the status of the organization and its understanding of the standard requirements. Any missing documents or additional documents required by the auditor will be requested.

In the case of a quality management system audit according to DAkkS procedures, an on-site visit may take place as part of the Level 1 audit. During this visit, additional information is gathered on the organization's readiness for the Level 2 audit and the resources required for this.

The main contents of the audit are:

- Review of the maturity of management processes; in particular, planning and the successful completion of internal audits and management reviews must be ensured by the time of the Level 2 audit.
- Review of the organization's core processes to assess the successful implementation of the management system; in the case of matrix procedures, this may require the inclusion of another location of the organization.
- Clarification of the scope of certification, particularly with regard to locations, activities, and scopes.

The audit leader prepares an audit report for the Level 1 audit, which is sent to the organization in good time before the Level 2 audit, giving it the opportunity to correct or supplement the management documentation and procedures in advance.

This is followed by consultation with the organization regarding the Level 2 audit, for which priorities are set.

As a rule, the Level 2 audit can be carried out at the organization at the agreed time, whereby the period between the Level 1 and Level 2 audits may not exceed six months.

If major gaps are identified after the Level 1 audit, these are detailed in the report. If necessary, it may be advisable or necessary to postpone the Level 2 audit date to give the organization an opportunity to close the gaps.

Stage 2 audit

After scheduling an appointment, the audit team conducts the Level 2 audit at the organization's location(s) based on test criteria and documentation for system audits. If specific technical problems need to be solved, a suitably qualified expert may be consulted.

The procedure is based on the relevant specifications of the corresponding certification systems and begins with an introductory meeting, followed by interviews with managers and employees, site visits, observations of activities and conditions, and a review of documents to collect evidence of compliance with all standard requirements.

In the final meeting, the lead auditor gives those responsible a verbal interim report to inform them about the status of the certification.

If deviations are identified, the organization is given the opportunity to analyze their causes and define measures to remedy the deviating condition by a date specified in the deviation report. The successful implementation of these measures must be confirmed by the auditor either by reviewing subsequently submitted documents or by conducting a follow-up audit on site before the certification process can continue. Complaints are reviewed for effective correction during the next audit.

Document reviews under MDR

Various document reviews are carried out for procedures under Regulation (EU) 2017/745, MDR.

If non-conformities are identified during the audit, the contractual partner has the opportunity to rectify them and resubmit the documents for review. A maximum of four audit cycles are permitted. A negative audit result in the fourth cycle automatically leads to termination of the conformity assessment procedure.

2.3 Certificate issuance / issuance of certificate of conformity

Within 10 working days, the audit leader/assessor prepares an audit report containing all the results of the assessment.

In the case of certification of a management system according to EN ISO 13485, the final decision on the issuance of a certificate lies with the certifier/certification committee. This issues the certificate upon successful completion of the entire process. In the case of conformity assessments according to MDR, the final decision lies with the final reviewer.

The certificate issued is valid for three years from the date of the certification decision, and certificates of conformity are valid for up to five years, with annual reviews taking place.

Berlin Cert certificates are available digitally, printed in DIN A4 size, and in various languages. The status of the certification is made publicly available.

2.4 Certification mark

The use of the certificate and the certification mark are part of the certification agreement concluded with the organization and are governed by the Berlin Cert examination regulations. In accordance with these conditions, organizations certified by Berlin Cert may use the certification

mark free of charge. They are entitled to present this mark in digital media, on letters, brochures, and information documents for advertising and image purposes.

2.5 remote audits

Berlin Cert has the option of using IT resources in audits in consultation with the organization (e.g., for remote audits). This saves travel time and reduces travel-related emissions. The organization's fundamental consent is required to include remote audits in the audit program. The possibility of remote audits is assessed by the lead auditor in consultation with the certification body/notified body and must be approved by the latter.

3 Maintaining certification

3.1 Verification audits

In accordance with the prescribed certification procedure, a prerequisite for the issuance of a certificate is the annual review of the management system by the auditor on site during the term of the certificate. The first surveillance audit after initial certification must be completed no later than 12 months after the date of the certification decision.

All subsequent verification audits shall be conducted at least once per calendar year. The dates shall be specified in the audit program. The audit shall not cover the entire scope of the initial audit, but shall be limited to the parts essential to the functioning of the management system, such as:

- internal audits and management review,
- handling of complaints, grievances, and incidents,
- effectiveness of the management system in terms of achieving objectives,
- evaluation of changes,
- ongoing operational control/management,
- Progress in terms of continuous improvement (including the rectification of any complaints from previous audits) and
- Use of symbols/other references to certification.

Other applicable elements of the standard are selected by the audit team and included in the audit plan. Otherwise, the procedure follows the implementation of a certification process.

The certification contract begins with the customer's order and includes both the (initial) certification audit and the subsequent review and recertification audits. In accordance with the current cost calculation, invoicing for audits in subsequent years will of course only take place after the respective services have been provided by Berlin Cert.

This postponement of the target date does not apply to audit dates that are carried out up to 14 days before the target date. In the event of a longer postponement of up to a maximum of 28 days, a request can be made to retain the old target date. To do so, a written request (by email with a brief explanation) must be submitted to Berlin Cert.

If it is not possible to assess compliance with the essential requirements on this basis, Berlin Cert GmbH will arrange or carry out any additional tests that may be necessary.

3.1.1 Special regulation MDR:

The interval between audits must not exceed 365 days.

The products to be tested will be 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 then invoice the customer for the purchase price.

Berlin Cert has the option of carrying out these tests in addition to or instead of an unannounced audit.

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

Unannounced 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 customer's premises and/or those of their important suppliers or subcontractors.

3.1.2 Changes to requirements

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

3.2 Transfer of an existing certification

It is also possible to change certification bodies within the validity period of a certificate . The assessment of the certification and the issuance of the certificate are carried out in accordance with

the provisions of the respective IAF guidelines.

Before a transfer can take place as part of a review, recertification audit, or during the year , a preliminary review (pre-transfer review) is required. The review is usually as a document review.

3.3 Maintaining certification in the event of extraordinary events

Organizations may be temporarily unable to conduct planned audits to maintain certification due to events beyond their control. Examples of such events include war, strikes, riots, terrorism, pandemics, floods, earthquakes, malicious attacks on computers, or other natural or man-made disasters.

In such cases, Berlin Cert may, at the request of the organization and after analyzing the risks involved, modify the audit program, postpone audits, or even extend the validity of certificates.

4 Recertification

Before the certificate or certificate of conformity expires, a recertification audit or re-conformity assessment is necessary. Before this process can begin, the company data available to Berlin Cert is compared with the contractual partner. On this basis, the audit effort and the audit program are then finally determined.

The recertification audit should take place early enough to ensure that the process is completed before the old certificate expires – usually at least 4 weeks in advance.

The procedure essentially follows the process for initial certification. However, the Level 1 audit is usually waived if there are no significant changes to the management system.

A recertification audit assesses the ongoing conformity and effectiveness of the management system as a whole in a Level 2 on-site audit and confirms its continued relevance and applicability to the scope of certification. Previous audit reports on surveillance audits are used for the assessment. A new certificate is then issued.

The on-site audit checks:

- Effectiveness of the management system in light of internal and external changes and its continued relevance and applicability within the scope of certification,
- the stated commitment to maintaining the effectiveness and improvement of the management system in order to enhance overall performance,
- the customer's management system and its performance with regard to compliance with legal requirements,
- Operational control/management of processes,
- Internal audits and management review,
- Management responsibility for the fundamental regulations of the management system,
- links between normative requirements, policy, performance objectives and targets, all applicable legal requirements, responsibilities, competencies, activities, procedures, findings from internal audits.

5 Appeals

Appeals against decisions made by the certification body can be submitted using the public appeal form or in writing by email to GUTcert. The deadline for submitting an appeal is one month from the date of notification of the decision.

6 Audits for special reasons

6.1 Extension of the scope

An extension of the scope can be carried out in connection with a review audit or in a separate audit. After receipt of the application, the organization will first receive a detailed list of the minimum documents to be submitted. These will be reviewed by the auditor/assessor, who will then inform the organization of any necessary measures. An additional audit may be necessary. In the case of waste management companies, an extension of the approval notice is requested from the approval authority. The organization will then receive a new certificate.

6.2 Unannounced and short-notice audits

In accordance with the accreditation rules, unannounced or short-notice audits may be carried out at certified customers in order to investigate serious complaints, check for significant changes, or reinstate suspended certifications. In these cases, the certification body takes particular care when appointing the audit team, as there is no possibility of objecting to members of the audit team.

7 Cancellation, suspension, restriction, and withdrawal of certificates

If the conditions for the validity of a certificate are no longer met, the certification body must take measures to prevent the use of this certificate/certificate of conformity or to ensure that the certification requirements are met.

Procedures for the cancellation, suspension, withdrawal, or reinstatement of certificates are documented. The status of each certificate is made publicly available.

7.1 Cancellation

A certificate is canceled if the certified organization no longer meets the conditions for continued validity of the certification through no fault of its own. This includes, in particular, bankruptcy, transfer to another organization, or cessation of the certified activity.

As soon as the certification body becomes aware of such facts, they are verified (usually by contacting the organization). If there are corresponding reasons, the certification contract must be terminated and the organization is requested in writing to return the certificate and to cease advertising with the certificate or the certification mark or to refer to the certification in any other way.

7.2 Suspension

If the specified period for completing the review process is exceeded or if the organization's certified management system still does not meet the requirements after the specified deadline for corrective action has expired, the validity of the certificate must be suspended. The suspension shall be communicated in writing, together with the requirement to cease advertising with the certificate or certification mark or otherwise referring to the certification until the suspension is lifted. A suspension may be granted at the request of the organization.

It may be granted for a maximum period of 6 months. A verification audit is carried out for reinstatement. Upon successful completion of the verification procedure, the suspension is lifted and the existing certificate will be 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.

7.3 Restriction of the scope

If the requirements for part of the scope of a certificate are permanently not met
If these conditions are not met, the scope of the certificate may be restricted by the certification body.

7.4 Revocation

A certificate must be revoked by the certification authority if

- a suspension of a certificate cannot be lifted on time, or
- the certification contract with an organization is terminated through the fault of the organization, or
- the organization does not meet the requirements of the standard even after the set deadline has expired, or
- the organization ceases operations permanently.

The organization will be requested in writing to return the certificate and to refrain from any further advertising using the certificate or certification mark, or otherwise to refer to an existing certification.

In case a), the certification contract must be terminated or a recertification procedure carried out, as appropriate.

The head of the certification body/notified body is responsible for the withdrawal of a certificate.