

1. Scope

These rules cover the following activities of the certification body of mdc medical device certification GmbH (in the following mdc):

- certification of quality systems according to QM standards (e.g. EN ISO 13485, EN ISO 9001, ...)
- Prequalification of service providers in the provision of aids according to § 126 SGB V

mdc's activities are based on the requirements of the respective standards mentioned above in their valid version. mdc applies standards and rules of the accreditation bodies to which mdc is subject to. Furthermore, it is acknowledged that mdc uses standards, guidelines, recommendations and working papers in the quality management certification process which are based on a broad national, European or international consensus. These general rules for certification are part of the general terms of business of mdc.

2. Application

The application is carried out in writing with forms provided by mdc.

The client declares:

- that according to the provisions of the contract, which was signed between him and mdc medical device certification GmbH, and the general terms of business of mdc medical device certification GmbH he will meet the requirements for the certification continuously and provide all relevant information and required documents or evidence,
- that he will implement changes of the certification requirements upon information by mdc,
- for quality systems to fulfill all obligations resulting from the certified quality system and to maintain the certified quality system adequate and efficient,
- that he has implanted a system for complaint evaluation in the certified quality system. The system has to include records of all complaints regarding fulfillment of the certification requirements. The records shall be made available to mdc on request. With respect to such complaints or deficiencies regarding certification requirements, suitable corrective actions have to be taken and documented.

3. Assessment

The client agrees that the accreditation body of mdc may observe certification audits or inspections in the scope of prequalification and assures their access to his – and if applicable within certification audits - to his suppliers' facilities.

4. Impartiality

Fundamental requirement to the certification/prequalification conducted by mdc is the impartiality to which mdc is fully committed to. The independence of personnel is checked within the employment phase and is also part of the selection of subcontracted external auditors, experts or inspectors. To assure the impartiality there is implemented a steering committee which represents members of all relevant interested parties. Necessary processes for avoiding and handling of conflicts of interests are implemented.

5. Enforcement of the Certification Rules

In cases where an client violates mdc's General Terms of Business and/or parts of them, mdc may take measures. These measures may be the agreement of corrective actions, a restriction of the certificate, a timely limited suspension or a withdrawal of the certificate. The suspension or withdrawal of the certificate in the area of QM certification will only occur by decision of the certification board.

The certificate can be withdrawn if one of the following facts will occur after issuance of the certificate:

- the legal requirements for the certified system of the attested prequalification are not fulfilled,
- the client does not accept the surveillance procedure,
- the certificate or the certification mark with mdc-Logo are misused,
- the client makes statements about certification of scopes which his certificate does not contain,
- the client uses the certification in a way that discredits mdc,

- the client makes statements that mdc regards as misleading and not authorized,
- the certificate or certification reports or parts of them are used in a misleading way,
- the client does not eliminate nonconformities identified concerning the normative base within a given period of time,
- the client does not fulfill the notification requirements.
- the client gives up his business activities because of financial or other reasons,
- the client gets into payment defaults despite mdc's reminders,

In case of a suspension or withdrawal of a certificate the client has the possibility to explain his position in advance. Exceptionally a withdrawal can be performed without this hearing if there is a special urgency for this measure.

Certificates which were declared as non-valid by mdc have to be returned in original or their destruction has to be confirmed in writing.

6. Use of certification, certificate and certification mark

The client is obliged to use his certification only according to the conditions mentioned in the rules concerning the Use of certification, certificate and certification mark. Moreover further legal, normative, guidelines, contractual and other requirements will be considered. If certification documents are made available by the customer to other parties, they may only be reproduced in their entirety.

7. Requirements for reporting

Beside the notifications required in the context of surveillance, the client undertakes to notify planned changes with regard to organization and location as well as - in the area of QM certification - with regard to production technologies relevant suppliers or subcontractors and product range at any time.

Notification obligations include information about any changes which potentially influence fulfillment of the certification requirements.

8. Complaints and formal appeals

Information on the submission and handling of complaints and appeals can be found in the General Terms of Business.