

1. Scope

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

- certification of quality systems according to EN ISO 13485, EN ISO 9001 and EN ISO 15378
- certification of medical devices according to MDD 93/42/EEC
- certification of in vitro diagnostic devices according to IVDD 98/79/EC.
- certification of active implantable medical devices according to AIMDD 90/385/EEC.

mdc's activities are based on the requirements of the respective standards mentioned above in their valid version as well as the standards and regulations for accreditation mdc is subject to.

mdc uses in the certification process standards, guidelines, recommendations and working papers which are based on a broad national, European or international consensus.

These general regulations for certifications 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 applicant declares:

- that he assures to fulfill all obligations resulting from the approved quality system and to keep the quality system adequate and efficient,
- that according to the regulations of the certification 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.

3. Assessment

The applicant agrees that the accreditation bodies of mdc may observe assessment audits and assures their access to his and his suppliers' facilities.

4. Impartiality

Fundamental requirement to the inspection, assessment and certification 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 and laboratories. To assure the impartiality according to the requirements of the ISO 17021 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 applicant violates mdc's general terms of business and/or parts of them, mdc may take necessary measures. These measures may be the agreement of corrective actions, a restriction in the scope of certification, a timely limited suspension or a withdrawal of the certification. In any case suspension or withdrawal will only occur by decision of the certification board.

The certificate can be withdrawn if one of the following facts will occur after granting a certification:

- the legal requirements for the system, device or category of devices covered by the certificate are not fulfilled,
- the device or category of devices do not fulfill the Essential Requirements in a way that patient, user or third persons are exposed to major risks or the devices do not fulfill the purpose defined by the manufacturer and the fault can not be removed in a planned and adequate time.

Furthermore the certificate can be withdrawn in particular if:

- the certificate or the certification mark with mdc-Logo are misused,
- the applicant makes statements about certification of scopes which his certificate does not contain,
- the applicant uses the certification in a way that discredits mdc,
- the applicant makes statements that mdc regards as misleading and not authorized,

- the certificate or reports or parts of them are used in a misleading way,
- the applicant does not accept the annual surveillance audits,
- the applicant does not eliminate non conformities concerning the normative base within a given period of time,
- the applicant gives up his business activities because of financial or other reasons,
- the applicant gets into payment defaults despite mdc's reminders,
- the applicant does not fulfill the notification requirements.

In case of a suspension or withdrawal of a certificate the applicant or his representative located in the EEA 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, CE-mark and certification mark

The applicant is obliged to use his certification only according to the conditions mentioned in the rules concerning the "Use of certification, certificate and certification mark".

7. Requirements for reporting

Beside the notifications which are requested by mdc in the context of the surveillance audit, planned changes in the location, organization, relevant suppliers, subcontractors, production technologies and/or product range must be notified. Further the applicant is obliged to inform mdc immediately about incidents or recall of the products in the sense of Article 10 of Directive 93/42/EEC, Article 11 of Directive 98/79/EC or Article 8 of Directive 90/385/EEC. Furthermore limitations regarding market activities (e. g. through verdicts or decisions by authorities) must be reported to mdc as well as cases in which authorities request the submission of the technical file of certified devices.

8. Liability

Liability through mdc is in particular limited to cases of premeditation or gross negligence. The height of the liability is limited to following amounts: € 3.000.000 for personal injury, € 2.000.000 for material damage and for property damage. All further claims are excluded. mdc is covered by a legally required liability insurance covering the above mentioned amounts.

9. Complaints and formal objections

Complaints and formal objections should be given in written form. mdc will give an acknowledgement of the receipt. The next step will be an impartial assessment and evaluation of the given facts with the aim of a fair and rapid solution finding. The appellant will be notified about the solution in written form. In case of a formal objection the arbitration committee may start the arbitration process. All information will be handled confidential.