

**1. Scope**

The services of mdc medical device certification GmbH (mdc in the following) are assessment, testing, certification and surveillance of:

- medical devices and quality systems of medical device manufacturers according to Annexes II, V and VI of MDD 93/42/EEC or Annexes IX and XI of Regulation (EU) 2017/745 as Notified Body
  - in-vitro-diagnostic medical devices and quality systems of manufacturers of in vitro diagnostics according to Annexes III, IV and VII of IVDD 98/79/EG as Notified Body
  - quality systems according to QM standards (e.g. EN ISO 13485, EN ISO 9001, ...)
  - providers of health care products as a certification body for prequalification according to §126 SGB V
  - providers of health care products as a QVH inspection body
- mdc offers these services through own staff or experienced subcontractors and test laboratories as well as through recognized co-operation partners.

All offers by mdc are based on the following general terms of business which apply to all services by mdc and are regarded as accepted after placing an order or filing an application.

In case there are different interpretations or translations of this general terms of business or other corresponding requirements compared to the German original the current German issue is valid.

Parts of these general terms of business are the following separate rules which are accepted after filing an application:

- the applicable process description
- the applicable rules for certification
- the contents of the application and certification contract
- the applicable rules for the use of certificates and symbols
- the applicable price lists.

Other terms of business which are in contradiction to these requirements can only become part of the contract if they have been accepted by mdc in writing. Silence on the part of mdc is not sufficient.

In general, all documents or reports are created in German or English language. If translations to the German document were additionally created, always the German version is binding.

**2. Offers, contents of the contract**

Offers always refer to the information available at the time of issue and they are not binding.

Content and range of duties of both parties to the contract result from mutual written declarations.

For performance of a certification procedure filing a written application and conclusion of a certification contract is compulsory. In case for any services, no application has been filed or contract has been concluded, the written confirmation of order is valid. If this is not available as well, the application of the client is relevant.

**3. Object of the contract**

Object and content of the contract is the agreed certification service whereas the order does not include certain assessment or certification results. All results refer only to the documents and objects submitted the observations of the on-site audit. The rights connected with the certificate or the approval are valid only after handing out the certificate or the approval.

**4. Duties of the applicant**

The applicant provides all required personnel, facilities and documents timely and in sufficient number. Documentation by the applicants is supplied in German or English language.

The applicant has to inform mdc about all procedures, facts and circumstances, which may potentially influence the task to be performed by mdc.

The applicant commits to submit on request his official commercial registration.

The applicant agrees that the bodies granting mdc authorization and permanent employees of mdc may observe audits or inspections and assures their access to his facilities as well as to facilities of his suppliers/subcontractors to be audited.

In case of audits required for special reasons or in case of unannounced audits being part of the certification requirements, the applicant also ensures access to his facilities and to facilities of suppliers/subcontractors.

In case the performance of audits or inspections may require measures for ensuring safety of mdc's personnel or such measures are requested by mdc, the applicant will implement these measures at his own expenses. Such measures may cover the complete stay for an audit from arrival to a country until departure from the country.

When sending in products the applicant guarantees to send them in an appropriate way and to pay attention to the relevant rules for dispatching.

If there are special risks to consider with the products (e. g. explosive, toxic, contaminated, special requirements for storing) the applicant has to make mdc aware of these circumstances by marking the products accordingly.

If copies of documents are not submitted in the number as requested by mdc, or if the applicant requests documents back before the end of the retention period, mdc can copy the documents at the applicant's expenses.

**5. Carrying out of the order**

mdc carries out the order by the help of trained staff, lead auditors, experts and test laboratories as well as co-operation partners according to the process description and, if applicable, according to the agreed schedule. mdc is obliged to choose and supervise all personnel and test laboratories carefully. By issuing a certificate mdc guarantees the validity at the time of issue.

mdc cannot guarantee to maintain all of its authorizations, however, is obliged to take efforts to secure the authorizations during the validity of a contract if the financial efforts are appropriate in relation to the conditions of the value of the contract.

**6. Dealing with documents and test products**

Documents and test samples submitted will be marked clearly and stored according to the required storing conditions.

After the end of the certification process documents and test samples will be stored for ten years following the expiry of the approval or they will be given back to the applicant at the instigation of mdc. The applicant has to store the documents and test samples for the time as defined by mdc.

**7. Mutual information duties**

mdc informs the applicant about the assessment and test results in writing. Furthermore mdc has to inform the applicant about facts that could endanger the assessment or testing. The applicant has the same responsibility.

**8. Complaints and appeals**

Complaints are considered to be negative statements made by clients, suppliers, other business partners or third parties concerning mdc and its services, provided that a fault on the part of mdc is suspected.

Appeals represent a questioning of the decision made by mdc in the course of a certification process (e.g. suspension, withdrawal or refusal of a certificate).

Complaints and appeals are to be submitted in writing; for this purpose the appropriate form can be used on mdc's homepage under "[Contact - Appeals and Complaints](#)".

The receipt of this written information will also be confirmed in writing. This is followed by an objective examination and evaluation of the circumstances by non-involved persons with the aim of a fair and timely solution to the problem. The complainant or appellant will be informed in writing of the results of the evaluation or problem-solving in the case of complaints and appeals.

If a client's objection is found to be clearly unjustified in the frame of an internal predecision process, it will be rejected. In all other cases an agreement with the appellant on the subject of the appeal shall be sought. If this is not successful, the appellant may request the intervention of an arbitration committee.

In this procedure, a competent and objective group of persons determined by the respective head of the certification body (arbitration committee) will examine the appeal and hear the appellant in writing and, if requested, in person. Based on this hearing, the arbitration committee shall take a decision regarding the granting, suspension, withdrawal or restriction of a certificate or notice.

If the head of the certification body was involved in the subject matter of the appeal, the members of the arbitration committee are determined by the deputy head of the certification body or, if applicable, the head of another business unit of mdc.

The appeal to the arbitration committee is charged to the appellant. Upon appeal, 50% of the procedural costs on which the appeal is based, but not less than € 5,000, will be invoiced as a down payment with immediate maturity. The actual costs will be calculated in consideration of the time required by mdc on the basis of the respective daily or hourly rates for assessment services of the price list on which the procedure is based. In case the appeal is not upheld, the appellant shall bear full costs. If the appeal is upheld mdc will bear the entire costs. If a compromise is achieved, the parties shall each bear half of the costs, unless another share is agreed upon. If the appellant does not agree with the result of the proceedings, he has the right to take legal action.

#### **9. Invoices and payment conditions**

Invoices are based on the valid offer formerly given to the applicant. Items which are stated but not rated be invoiced are based on the mdc price list valid at the application date. Unannounced audits, verification of manufactured products and special services will be charged according to the mdc price list at the date of providing the service.

mdc can charge advance payments for services and travel expenses up to the full amount of the contract.

Invoices may be issued after individual service items provided. Application fees can be charged right after receiving the order. Annual fees will be due at the first day of the month in which the certificate has been issued, but they can also be charged together with invoice for the annual surveillance audit.

Invoicing may be made by foreign branches or tax representations.

If not otherwise noted all payments are due right after receipt of the invoice or after a request for payment. Payments have to be transferred without any deduction and with quotation of the invoice number as well as free of charge to the account mentioned. After the expiry of the period of time allowed for payment which is mentioned on the invoice the applicant gets into default and mdc is entitled to charge interests of delay in the height of common interests for bank loans.

If an invoice will not be paid after a reminder and a reasonable extension mdc is entitled to conduct measures like judicial collection proceedings, the suspension and withdrawal of the certificate or the cancellation of the contract.

If the contract has to be cancelled because of the above mentioned reason mdc has the right to charge all services provided and a compensation of up to 10% of the remaining amount of the offer regarding the aimed or actual period of validity of the certificate. If certificates or approvals have been issued during the validity of the contract they will be withdrawn.

If mdc does not receive any written objections concerning invoices within 14 days after reception of the invoice the invoice is regarded as accepted.

To set payments off against the claims of mdc is only permitted if the counter demand is undoubtedly or legally valid.

#### **10. Guarantee**

mdc does not guarantee the achievement of certain assessment results.

mdc's guarantee does contain only and is limited to carrying out the order according to the agreed contract carefully.

If the carrying out of the order shows any shortcomings the applicant has to set a deadline for mdc to eliminate them.

If mdc accepts certain services as not sufficient, mdc will correct or render them anew at mdc's choice and expenses. If the correction is not satisfying as well the applicant can reduce the invoice or cancel the contract. If a correction is not possible there is no deadline necessary.

Claims for guarantees are in lapse twelve months after the handing over of assessment or final reports regardless of the client's knowledge.

#### **11. Delays during the carrying out of the order**

mdc does not guarantee a carrying out of the order according to a certain time schedule, especially not in cases of acts of God or delays that are caused by the applicant.

If the delay is caused by mdc the applicant has the right to cancel the contract if he had set a deadline for working on the corrections after shortcomings and mdc has missed this deadline.

#### **12. Liability**

The applicant is liable according to the general legal requirements.

Unless stated differently in the specific certification rules mdc is only liable for damages caused by breaches of duty:

- a) for damages resulting from injury to life, body or health caused by a breach of duty by mdc or a legal representative or vicarious agent of mdc
- b) for damages resulting from the intentional or negligent breach of essential contractual obligations (cardinal obligations) by mdc, by one of mdc's legal representatives or a vicarious agent of mdc. Essential contractual obligations (cardinal obligations) are obligations whose fulfilment is essential for the proper execution of the contract and on whose compliance the client regularly relies.
- c) for damages resulting from an intentional or grossly negligent breach of obligations other than the aforementioned cardinal obligations by mdc or a legal representative, executive employees or vicarious agents of mdc
- d) for damages that fall within the scope of protection of a warranty (assurance) or guarantee of quality or durability granted explicitly by mdc.

In the event of an simple negligent breach of an essential contractual obligation mdc's liability is limited to the amount of damages typically to be expected and foreseeable by mdc at the time of the conclusion of the contract provided that mdc applied due diligence. Damages resulting from injury to life, body or health are excluded from this limitation.

Claims for compensation by the client that exist according to the rules set out above become time-barred in case of a simple negligent breach of mdc's obligations one year after the beginning of the statutory limitation period. This does not apply to damages resulting from injury to life, body or health.

#### **13. Exemption of liability**

The applicant exempts mdc of all claims of third parties resulting of personal injuries caused by products handed in by the applicant as test products.

**14. Validity of contracts and cancellation**

Certification contracts are valid until the expiry of the relevant certification, unless otherwise agreed during the offer process or the application process.

The applicant and mdc are entitled to withdraw from the contract if no significant progress has been made within six months after the application has been submitted and the client is responsible. After the effective cancellation mdc will hand out assessment results, reports and decisions on certifications to the applicant.

The applicant is obliged to pay for all services done up to then. mdc is entitled to cancel the contract because of important reasons at any time. Such reasons could be the misrepresentation of facts by the applicant during the certification process or in fundamental changes of the requests of the applicable laws or of the bodies granting to mdc authorization. In the latter case mdc immediately offers the continuation of the contract according to modified conditions.

After the issue of a certificate the applicant can only cancel the contract because of important reasons. In case of a premature termination of contract annual fees will be due for each 12 month of validity.

The cancellation has to be handed in as certified letter with an acknowledgement of receipt.

**15. Confidentiality**

mdc is obliged to use all test samples, documents and information only for the purpose of assessment and certification.

They can be made available for third parties only after the applicant's agreement. This is also valid for other results and knowledge of the assessment. Documents and information made available by subcontractors of the applicant or others involved in the procedure are also subject to confidentiality and are accessed to the applicant only after the agreement of the provider of information. Excluded are assessment results, which will be directly communicated to the applicant.

Excluded from confidentiality is the legal obligation to give information to the competent authorities, other Notified Bodies and other bodies granting mdc authorization.

All employees and third parties involved in the assessment or certification are also bound to keep all information about the certification confidential.

Information regarding issued certificates according quality standards will be published by lists. A list of all withdrawn certificates will be released to the public. Further information regarding issued, discontinued, restricted, denied or withdrawn certificates will be given on inquiry. These inquiries are accepted in written form on note paper with original letterhead by stating basic information about the company, legal or normative basis and scope.

**16. Place of execution and jurisdiction**

The place where the contract is executed and the only court of jurisdiction is the registered place of business of mdc (currently Stuttgart).

**17. Applicable law**

The contract between mdc and the applicant is subject to German law only.

**18. Ineffectiveness of certain parts**

As far as one part of the contract between mdc and the applicant or of this general terms of business is or will not be valid or ineffective because of any reason the validity of the remaining parts are not touched. The parties are obliged to replace the ineffective part by an effective one that comes as close as possible to the interests of both parties. Until this replacement the legal requirements are valid.