

**1. General and scope**

In the case that gender-neutral formulations are not used in the General Terms of Business (GTB) and all other documents of mdc, these are to be understood as gender-neutral in any case - regardless of which form is used in the individual case.

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

- medical devices and quality management systems according to Regulation (EU) 2017/745 as Notified Body,
- in-vitro-diagnostic medical devices and quality management systems of manufacturers of in vitro diagnostics according to Regulation (EU) 2017/746 as Notified Body,
- quality systems according to QM standards,
- providers of health care products as a certification body for prequalification according to §126 SGB V,

Furthermore, mdc carries out the surveillance of legacy devices according to Article 120 of Regulation (EU) 2017/745 or Article 110 of Regulation (EU) 2017/746.

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 of 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.

If the content of the applicable separate regulations is described more precisely than in the GTB, these detailed regulations must be applied in case of doubt. 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. Within the scope of prequalification, a contractual relationship is established through a written application and confirmation by mdc. 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. In particular, the contract does not extend to the achievement of a specific assessment, test or certification result. All results refer only to the documents and objects submitted the observations of the on-site audit. The client's rights connected with the certificate are valid only after handing out the certificate or the approval.

**4. Duties of the client**

The client shall provide mdc with all documents, products and personnel support necessary for the execution of the order in due time and in the form and quantity required by mdc. Only German and English are accepted as correspondence languages. Documents of the client shall be submitted in

German or English and made available in the audit for inspection and, if necessary, to be taken along. The client has to inform mdc about all procedures, facts and circumstances, which may potentially influence the task to be performed by mdc.

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

The client 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 client 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 client 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 client 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 client 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 client requests documents back before the end of the retention period, mdc can copy the documents at the client'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. The decision as to whether an on-site assessment is replaced in full or in part by IT-supported audio/video conferencing solutions is the sole responsibility of mdc. The selection of the IT-supported audio/video conferencing solution shall be made by mdc taking into account the data protection requirements.

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 client at the instigation of mdc. The client has to store the documents and test samples for the time as defined by mdc.

**7. Mutual information duties**

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

**8. Complaints and appeals****8.1. Complaints**

Complaints should preferably be submitted in writing by using the form on the mdc website.

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. The receipt of a complaint is confirmed in writing. This is followed by an objective examination and assessment of the facts by persons not

involved. The complaining party will be informed of the results in writing, taking into account the requirements of confidentiality and any official requirements.

## 8.2. Appeals

Appeals must be submitted in writing; the form on the mdc homepage can be used for this purpose. Appeals represent a contestation to the decision made by mdc within the framework of a certification procedure (e.g. suspension, withdrawal or refusal of a certificate).

The receipt of an contestation is confirmed in writing. This is followed by an objective examination and assessment of the facts by persons not involved. The appellant will be informed in writing of decision of the head of the certification body, taking into account confidentiality requirements and any official requirements.

If the appellant does not accept the decision, he can initiate an extended appeal procedure.

In this procedure a team of competent and objective persons determined by the respective head of the certification body will examine the appeal and hear the appellant in writing and, if requested, in person. Based on this hearing, this team shall take a decision regarding the granting, suspension, withdrawal or restriction of a certificate. The respective head of the certification body includes this recommendation in its final decision, but does not have to follow this recommendation.

If the head of the certification body was involved in the subject matter of the appeal, the team of the extended appeal procedure are determined by the deputy head of the certification body or, if applicable, the head of another certification body within the mdc.

In the event that the appeal is not upheld, the appellant shall bear the costs of the extended appeal procedure. The costs are calculated according to the time spent by mdc on the basis of the respective daily or hourly rates for assessment services in the price list on which the procedure is based.

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 or the order confirmation formerly given to the client. Items which are stated but not rated be invoiced are based on the mdc price list valid at the application date.

In the event of increased overhead and/or procurement costs, mdc is entitled to increase the prices as shown in the offer and in the price list valid at the time the order is placed on 01 April of each year by the change in the producer price index for services published by the Federal Statistical Office of Germany compared to the previous year. This shall be done by written notification, which must be sent at least one month before the intended effective date. If the price increase does not exceed 5% per contract year, the client shall not have any extraordinary right of termination on the occasion of such price increase. In the case of a price increase of more than 5% per contractual year, the client shall be entitled to terminate the contractual relationship with effect from 01 April of the respective calendar year. Otherwise, the changed prices shall be deemed agreed upon after expiration of the change period. 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 client gets into default and mdc is entitled to charge interests of delay in the height of 8 percentage points above the base interest rate currently published by the Deutsche Bundesbank.

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.

In the event of premature termination of the contractual relationship, mdc is entitled to charge for all services rendered as well as a compensation lump sum of up to 10% of the remuneration to be paid until the end of the fixed contractual term. The client reserves the right to prove a significantly lower damage. The aforementioned obligation to pay compensation does not apply if and insofar as the client terminates the contractual relationship prematurely on justified grounds, in particular by extraordinary termination.

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 client 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 client 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 client.

## 12. Liability

The client 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 of mdc 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 client exempts mdc of all claims of third parties resulting of personal injuries caused by products handed in by the client for testing.

**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 client 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 certificates to the client.

The client 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 client 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 client 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 given test samples, documents and information exclusively for the agreed activities. mdc imposes this confidentiality on all its employees and, where applicable, on third parties involved in the assessment, evaluation or certification.

Test samples, documents and information may only be made accessible to third parties only after the client's agreement. This also applies to other results and findings obtained in the course of the agreed activities. Documents and information made available by subcontractors of the client or others involved in the procedure are also subject to confidentiality and are accessed to the client only after the agreement of the provider of information. Excluded are assessment results, which will be directly communicated to the client.

Excluded from confidentiality is the obligation to give information to the competent authorities, other Notified Bodies and other bodies granting mdc authorization. This duty to provide information may relate to all information and documents of the principal. Should such disclosure of confidential information occur, the client concerned shall be informed of the facts, provided that this does not conflict with any legal requirements or requests by authorities.

If mdc sends reports to other recognising bodies or authorities at the request of the customer as part of approval procedures, this will occur only with the written consent of the customer.

Information regarding issued certificates according quality standards will be published by lists. A list of all withdrawn certificates is published. Further information on certificates issued, suspended, restricted, refused or withdrawn is provided within the framework of the legal and normative requirements. With the exception of authorities and authorizing authorities and other certification bodies, requests in this regard must be made in writing on original letterhead, giving appropriate basic information on the company, 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 client is subject to German law only.

**18. Ineffectiveness of certain parts**

As far as one part of the contract between mdc and the client 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.