

General business conditions of DQS Medizinprodukte GmbH, hereinafter referred to as “DQS MED”, for freely contracted services, particularly assessment and audit activities on behalf of contracting parties, hereinafter referred to as “client”.

1. Scope

1.1 These conditions apply to contracts agreed between DQS MED and its clients, unless otherwise agreed in written form or regulated by a statutory authority.

In the following text, audits and assessments are referred to as “assessments” and auditors and experts as “assessors”, audit and assessment reports are referred to as “assessment reports”. The certification documents are referred to as “certificates”.

1.2 The client accepts the General Business Conditions and prices of DQS and the “DQS Auditing and Certification Regulations” in their current version at the time of order placing, as well as the prices agreed in the order confirmation.

1.3 Contrary or deviating terms and conditions by single clients are basically not accepted. Only in case of advance explicit written acceptance by DQS, they shall be binding.

1.4 Subsidiary agreements, commitments and other declarations by the employees of DQS MED or the experts involved by them are only binding if they have been confirmed in writing by DQS MED. This also applies to amendments to this clause.

2. Service delivery

DQS MED certifies, audits and assesses its client’s management system, or part thereof, with the aim of determining its conformity with agreed requirements including the effectiveness of the management system or parts of it. The client receives an assessment report and/or a DQS MED certificate or statement of conformity. Management system audits are performed at the client’s place of operations. DQS MED is independent, neutral and objective in its assessments. Performance of services is subject to the provisions laid down in the current issue of the “DQS MED Auditing and Certification Regulations” (www.dqs-med.de), which are binding for both parties. Scope and extent of services delivered by DQS MED are specified in writing at the time of order placing; partial delivery is permitted. Parties agree on the exact dates of the proceeding separately. Where during proper performance of the order, changes and/or expansions to the original extent of the order are identified, these additions shall be agreed upon in writing by both parties in advance. Insofar as changes or expansions make it unreasonable for the client to adhere to agreed provisions, they have the right to withdraw from the contract. In doing so, however, the client is required to pay the fee agreed or, where there is no such agreement, a suitable fee.

3. Duties of the client

The client shall make available to DQS MED all information and documents necessary for the contracted services to be delivered; completely, diligently, and in a timely manner.

The client shall point out all procedures and circumstances that may be significant to the delivery of contracted services, without prompting. Unless the above-mentioned items have been complied with, the delivery of services will take place at the sole risk of the client, provided there is no contributory negligence on the part of DQS MED

4. Confidentiality, copyright, data security

DQS MED observes business confidentiality, taking precautions to ensure that written expertise or any other facts or documents made available in the context of service delivery regarding the client and the subject matter are not forwarded, exploited, or publicized without authorization. DQS MED may copy written documents, which have been made available to it for review or during service provision, for its own records. Insofar as written expertise, evaluation results, etc. have been created in the context of the order, which are subject to copyright protection, DQS MED grants the client a non-exclusive, non-transferrable right of use, as far as necessary in accord with the contractually prescribed purpose. No further rights are granted; in particular, the client is not authorized to modify written expertise, evaluation results, and the like. DQS MED also processes and uses personal data for their own purposes within DQS Group only. To this end, DQS MED also employs automatic data processing. In order to comply with the data security requirements of the appendix to Section 9 of the German Data Protection Act (BDSG), DQS has implemented measures of a technical-organizational nature designed to ensure the security of stored data and data processing. Employees involved in processing have been committed to the BDSG and to the strict adherence to all data security regulations.

5. Warranty

The warranty of DQS MED covers only the services expressly stated in the order. In the case of certification services, DQS MED is obliged to issue the certificate, provided the respective preconditions have been fulfilled. Insofar as DQS MED provides general services, the parties agree that DQS MED owes only services, not any specified success. Any decisions based upon the services delivered are incumbent upon the client alone, within their own sphere of risk and decision-making.

6. Liability

Irrespective of legal basis, DQS MED, its vicarious agents and auxiliary persons, may be held liable for damages only in case of intent or gross negligence, or in case of negligent breach of an essential contractual duty (“material duty”). In case of a breach of essential contractual duties, the liability of DQS MED is always limited to the extent of

the foreseeable damage typical for the contract at the time of its closing. Liability for collateral damages, to include collateral damage typical for the contract, is exempt. Otherwise, the liability of DQS MED is limited to twice the value of the order value, with a maximum of EUR 100,000 per business transaction and EUR 250,000 per calendar year.

7. Terms of payment

7.1 For the calculation of services, the respective and currently valid prices of DQS MED apply, unless a fixed fee or other basis for calculation has been expressly agreed upon. Invoices will be issued following each stage of performance and are due for payment in full within ten days from the date of the invoice, without deduction. In case of delayed payment, DQS MED is entitled to charge interest at the current bank rate.

7.2 Reasonable cost advances up to full amount for services and bills to be provided may be required and / or installments corresponding to the services already provided can be issued. Partial invoices do not have to be designated as such. The receipt of an invoice does not mean that DQS MED has completely settled the order by this.

7.3 The according to point 7.2. and/or acc. to the final invoice invoiced remuneration, after acceptance of the work, is due 10 days after date of the invoice, unless otherwise agreed.

7.4 The remuneration is exclusive of the legal value added tax in the respectively valid legal amount. The sales tax is shown separately in the invoice.

7.5 Complaints regarding invoices of DQS MED must be sent in writing, within a limitation period of 14 days after receipt of the invoice.

7.6 DQS reviews its prices on a regular basis. If rising overhead or procurement costs require an adaption of current prices, the increase will be notified 3 months before it takes effect. Price increases or other fees by third parties, reporting- and certification fees and other charges are excluded from notice 3 months in advance. Existing prices will still apply to services that have already been confirmed in writing.

8. Deadlines and due dates

DQS MED and the client schedule appointments for audits as far in advance as possible. Appointments are confirmed in writing. In case a confirmed appointment cannot be maintained by reason of the client, DQS may charge the client for expenditures actually incurred in preparing for this appointment. If the client cancels less than eight weeks before the date of service provision, DQS shall bill the client 80% of the contract’s value, including travel costs incurred and cancellation fees.

If the client cancels less than seven working days before the date of service provision, DQS MED shall bill the client 100% of the contract's value, including travel costs incurred and cancellation fees.

9. Duration and termination

9.1 The contract is concluded for one certification cycle from the date of order placing. 9.2 The client may issue a written notice of termination a minimum of six weeks to the end of the quarter, without giving reasons.

In the case of termination by the client, DQS MED reserves the right to charge for services already provided. If the client terminates less than eight weeks before the date of service provision, DQS MED shall bill the client 80% of the contract's value, including travel costs incurred and cancellation fees. If the client terminates less than seven working days before the date of service provision, DQS MED shall bill the client 100% of the contract's value, including travel costs incurred and cancellation fees.

10. Jurisdiction and choice of law

The court of jurisdiction is Frankfurt am Main. German law applies to the exclusion of the conflict of laws of international private law (IPR) and the United Nations Convention on contracts for the International Sale of Goods (CISG).

11. Deviating agreements

Deviating or additional agreements must be made in writing. Should individual provisions of the contractual agreements - including the terms and conditions - be ineffective, this does not affect the validity of the remaining provisions. The parties shall immediately replace the invalid provisions with those which come as close as possible to the meaning of the invalid provisions.

12. Additional requirements

In addition to the above conditions, the specific requirements to the individual standards apply, each in their respective valid version including their supplementary interpretations.

All previous General Business Conditions are hereby rescinded.