

GENERAL BUSINESS CONDITIONS OF DQS MEDIZINPRODUKTE GMBH
VALID FROM 01.MAY.2022

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", auditors and experts as "assessors", audit and assessment reports are referred to as "assessment reports" and the certification documents, certificates and confirmations are referred to as "certificates".
- 1.2 The client accepts the General Business Conditions and prices and the "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 not accepted on principle.
- 1.4 Subsidiary agreements, commitments and other declarations by employees of DQS MED or 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 parts thereof, as well as the technical documentation of medical devices in the legally regulated area, with the aim of determining its conformity to specified or agreed requirements, including the effectiveness of the system or parts thereof, as well as the safety and essential performance characteristics of medical devices within the legally regulated area. The client receives an assessment report and/or a DQS MED certificate or statement of conformity. Management system assessments are performed at the client's place of operations. This does not apply in particular to audits which are performed without the physical presence of the assessor at the client's place of operations ("**remote audits**") as well as technical documentation. 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; the execution of the order can be carried out in project stages according to the offer. Partial delivery is permitted. Parties agree on the exact dates for the individual project stages separately. Where during proper performance of the order or the individual project stages, 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. An advance written agreement however is

not necessary as far as it is mandatory according to Number 5.2 (Non-issuance of the certificate) of the "DQS Auditing and Certification Regulations" for closing nonconformities or conditions required for issuing the certificate. 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

- 4.1 DQS MED, its vicarious agents and auxiliary persons observe 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.
- 4.2 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-transferable right of use to use the work results for the contractually intended or typical purpose of use. No further rights are granted; in particular, the client is not authorized to modify written expertise, evaluation results, and the like. Disclosure to third parties is only permitted within the scope of the intended use.
- 4.3 DQS MED processes personal data in accordance with the applicable legal provisions, in particular the EU General Data Protection Regulation ("GDPR") and in Germany the Federal Data Protection Act ("BDSG"). DQS MED shall oblige the employees and vicarious agents assigned to execute the order to maintain confidentiality (data secrecy), unless they are already under a general obligation to do so. In this context, DQS MED will process personal data of the client for its own purposes within the scope of fulfilling the contract. Any further processing requires separate permission. If DQS processes personal data within the scope of contract processing for the client, the parties will conclude a separate agreement on this in accordance with Section 28 of the German Data Protection Act (DSGVO). Details can be found in our detailed data protection information.

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. DQS MED, its vicarious agents and auxiliary persons shall be liable for damages resulting from slight negligence insofar as an essential contractual duty ("material duty") has been breached or if DQS MED has expressly warranted the quality of the contractual performance. However, in the event of a slightly negligent breach of essential contractual duty, DQS MED shall only be liable for the foreseeable damage typical for the contract at the time of its closing. Essential contractual duties are those duties whose fulfillment characterizes the contract and on which the client may rely.

DQS MED is fully liable for damages resulting from intent, breach of warranty, delay with a binding delivery date or injury to life, limb or health in accordance with the statutory provisions.

Liability for collateral damages, to include collateral damages typical for the contract, is exempt in case of slight negligence. Otherwise, in the event of slight negligence, DQS MED's liability is limited to the typical contractual and foreseeable average damage.

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 of services and bills to be provided may be required. 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 remuneration is exclusive of the legal value added tax in the respectively valid legal amount. The sales tax is shown separately in the invoice.
- 7.4 Complaints regarding invoices of DQS MED must be sent in writing, within a limitation period of 14 day after receipt of the invoice.
- 7.5 DQS MED reviews its prices on a regular basis. An adaption 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 the aforementioned notification period. 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 audit 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 MED 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 MED shall bill the client 80% of the contract's value, including travel costs incurred and cancellation fees. If the client cancels fewer 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.

9.2 The placed order may be terminated by the client in writing without giving reasons with a notice period of six weeks to the end of each quarter. In case of termination by the client, DQS MED reserves the right to charge for services already provided but not yet invoiced. 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 plus any travel expenses actually incurred in connection with the order placement or cancellation fees for travel already booked. 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 plus any travel expenses actually incurred in connection with the order placement or cancellation fees for travel already booked.

9.3 DQS MED may only terminate upon good cause shown. Good cause shall be deemed to exist, in particular, in the event of non-fulfillment of the client obligations specified in sections 3 and 7 of these terms and conditions as well as in accordance with sections 5.3.2. (Withdrawal) and 5.3.3. (Annulment) of "DQS Certification and Assessment Regulations".

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



and the data protection conditions. With this issue, all of our previous general business conditions cease to be valid.

PRIVACY POLICY

1 **Controller**

The controller pursuant to Article 4(7) for processing personal data is

DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main
Federal Republic of Germany

2 **Data protection officer**

The controller appointed a data protection officer. The data protection officer is available at datenschutz@dqs-med.de.

3 **Purpose of processing and legal basis for processing;**

Personal data is processed by the responsible party while preparing offers, initiating contracts and performing the main and ancillary contractual services pursuant to Article 6(1)(b) GDPR. Storage is carried out according to the statutory storage periods and may be extended, if necessary, in accordance with Article 6(1)(f) GDPR for the protection and defense of legal claims. Furthermore, personal data may be processed in joint responsibility for ensuring quality of service in the respective competent unit of the group of undertakings for the legitimate interest pursuant to Article 6(1)(f) GDPR. For advertising and marketing purposes, personal data is processed with consent pursuant to Article 6(1)(a) GDPR. It is possible to object to processing pursuant to Article 6(1)(a) and (f) of the GDPR at any time for the future, whereby an objection in relation to Article 6(1)(f) is subject to a balancing of interests.

4 **Recipients or categories of recipients of personal data**

Personal data may be transferred to and processed by other companies of the DQS Group under joint responsibility or under the terms of a contract agreement for the purpose of fulfilling the contract and measuring service quality. If personal data is transferred to a third country (outside the scope of the GDPR), this is done exclusively for contract fulfillment and under appropriate guarantees in the form of an adequacy decision of the EU Commission or the provisions of a contract pursuant to Article 46(c) GDPR, available on request. The Controller reserves the right to transfer the processing of personal data to suitable service companies under the conclusion of data protection agreements.

5 **Rights of data subjects**

- Pursuant to Art. 7 (3) GDPR, consent for future use may be withdrawn at any time.
- Pursuant to Art. 15 GDPR, the data subject may obtain information about personal data. In particular, request information about the processing purpose, the category of personal data, the categories of recipients to whom your data have been or will be disclosed, the

planned storage period, the existence of a right to rectification, erasure, restriction of processing or objection, the existence of a right to lodge a complaint, the source of the data if not collected by the controller, and the existence of automated decision-making procedure, including profiling, and, if applicable, meaningful information about its details;

- Pursuant to Art. 16 GDPR, the data subject has the right to obtain from the controller, without undue delay, the rectification of inaccurate or incomplete personal data stored by the controller;
- Pursuant to Art. 17 GDPR, the data subject has the right to obtain the erasure of stored personal data, unless the processing is necessary for exercising the right of freedom of expression and information, for compliance with a legal obligation, for reasons of public interest, or for the establishment, exercise or defense of legal claims;
- Pursuant to Art. 18 GDPR, the data subject has the right to obtain restriction of processing personal data if the accuracy of the data is contested, if the processing is unlawful but erasure is refused, and if the data controller no longer needs the data but the data subject requires it for the establishment, exercise or defense of legal claims, or if the data subject has objected to the processing pursuant to Art. 21 GDPR;
- Pursuant to Art. 19, there is the right of the controller to communicate any rectification or erasure of personal data or restriction of processing carried out in accordance with Article 16, Article 17(1) and Article 18 to each recipient to whom the personal data have been disclosed, unless this proves impossible or involves disproportionate effort. The controller shall inform the data subject about those recipients if the data subject requests it.
- Pursuant to Art. 20 GDPR, the data subject has the right to receive personal data provided in a structured, commonly used and machine-readable format or to request that the data be transferred to another controller; and
- Pursuant to Article 77 GDPR, the data subject has the right to lodge a complaint with a supervisory authority.
- Personal data are not processed based on automated processing - including profiling.

Recipient of all data subject rights is DQS Medizinprodukte GmbH.