

DQS Auditing and Certification Regulations

of DQS Medizinprodukte GmbH hereinafter referred to as "DQS MED" – valid from January 1, 2018

1. Auditing and Certification Services

1.1 Scope and Applicability

These DQS Auditing and Certification Regulations apply to all auditing and certification services offered and rendered to clients of the international DQS Group, including all its subsidiaries and partners. A current list of all members of the DQS Group is available at www.dqs-holding.com. These regulations apply throughout all stages of the auditing or certification process, including but not limited to service offers and quotations, contracts, purchase and/or work orders, schedules and addendums agreed to between DQS and Client, unless it is otherwise explicitly agreed in writing or so prescribed by statutory instruments. These Auditing and Certification Regulations become effective as of January 1st, 2018 and remain valid until a new version is issued and published. The current version of these regulations is available in German and English language on the website of DQS MED (www.dqs-med.de) and can be requested from DQS MED.

1.2 Definition of terms

"Client" stands for customers and any organization that inquires about or receives any DQS auditing or certification service, including their representatives, who act on their behalf. "DQS" stands for any group members of the international DQS Group, including its subsidiaries and partners, who offer and/or deliver auditing and certification services to clients. In some cases one group member may become the contractual local partner of a client, while a specific service may be delivered partially or in full by another group member. "Auditor" stands for assessors, auditors and experts, who are assigned to an auditing and certification process on behalf of the DQS group.

1.3 Auditing and Certification Services

The auditing and certification of a management system or a product by an independent, competent third party, such as DQS, generates valuable benefits for the client. A DQS certificate will serve as evidence for a suitable and effective management system or compliant product with the capability to continuously meet customer expectations as well as regulatory and statutory requirements. During an audit, qualified and experienced auditors review the management system and its processes or products for ongoing suitability and effectiveness in light of changing markets and environment. By identifying improvement potential, auditors enhance the organization's ability to meet established goals and objectives, thus enhancing sustainable success for the client. With a DQS certificate customers may place confidence in the client and the certified management system or product, which has been audited and certified to recognized standards and specifications.

1.4 Reference to individual contract and commercial terms

1.4.1 These conditions apply to contracts agreed between DQS MED and its customers,

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 report", certification documents are referred to as "certificates".

1.4.2 The customer accepts the General Terms and Conditions, the Audit and Certification Regulations and the Price List in their current versions as well as the prices as agreed in the order confirmation.

1.4.3 Differing terms and conditions from individual customers are generally not accepted unless they are explicitly confirmed in writing.

1.4.4 Side agreements, commitments and other statements from employees of DQS MED or from involved assessors become only binding, if they are confirmed in writing by DQS MED. This applies also to changes of this clause.

2. The Certification Process

DQS audits the Client's management system or product, or parts thereof, with the goal of determining its conformity with agreed and acknowledged requirements, such as international, national or sector-specific standards or specifications. The respective certification process may involve one or more steps, usually ending with an audit report, which documents the audit results. In the case of certification services, DQS will issue a customer-specific certificate, confirming conformity to the respective requirements, when the fulfillment of all applicable requirements has been evident. If nonconformities with requirements of the respective standard or specification have been identified during an audit, corrective action shall be planned and carried out by Client within a specified time frame. Certificates will only be issued after the effective deployment of suitable corrective action has been demonstrated. The scope and duration of validity shall be stated on the certificate. DQS and Client agree that the evaluation and/or certification of the Client's management system(s) or products shall be performed in accordance with the applicable standards, the industry related requirements (if applicable) and the Auditing and Certification Agreement, including this document and any documents attached thereto or referred to therein. DQS is independent, neutral and objective in its audits and certifications. Audits are performed at Client's place of operations. The type, extent and time schedule of the procedure are subject to separate agreement by the parties. DQS strives to minimize any disturbances of the business process while conducting the audit on Client's premises. The Certification Process for management systems will generally include the steps mentioned in the pricelist.

3. Rights and Obligations of Client

3.1 Maintaining the Management System

In order to obtain and maintain a certificate, the Client shall implement and maintain a documented management system which fulfills the requirements of the selected standard or

specification. The Client shall provide evidence of conformity and effectiveness of the audited management system or product, readily available for auditing by the assigned audit team. The Client shall undertake all necessary actions to ensure that the management system is maintained in a conforming and effective manner at all times. The Client shall be notified of any changes to the certification program or new or revised requirements. In case the certification applies to ongoing production, the Client shall ensure that the certified product continues to fulfill the system or product requirements. DQS shall verify the implementation of changes by the Client and initiate required measures in the certification process.

3.2 Burden of Production ("accessible information" according to ISO/IEC 17021)

The Client ensures that DQS has access to all necessary information and the requisite facilities to perform the assigned audit tasks. The Client and their representatives commits to provide DQS with accurate and complete information in a timely manner concerning all processes which may be significant to the certification. This relates in particular to the scope of a certification. Within the scope of certified management systems, all records relating to complaints and their corrective actions shall be presented to DQS upon request. When necessary, the participation of observers in the audit shall be permitted.

3.3 Notification of Changes

The Client is obliged to inform DQS without delay of any changes, which may influence the certified management system or the certified products. This applies in particular to the legal, economic or organizational status or the ownership, organization and management, changes to the product or the production method, contact data and production facilities or sites and important changes to the quality management system, the purchase/ sale of all or a portion of the company, any change in ownership, major changes in operations, fundamental alterations in processes or the filing for bankruptcy or composition proceedings. In any of these cases, DQS will consult with Client and determine how the certificate may be maintained.

3.4 Independence of Auditing and Certification

Client is obliged to avoid anything that might compromise the independence of the employees and auditors of DQS. This applies in particular to offers of consultancy, offers of employment, both salaried and sub-contracted, to separate agreements about fees or other monetary rewards.

3.5 Right to reject Auditor

Prior to confirmation of the audit date, the Client is entitled to review and reject the auditor(s) assigned by DQS with proper justification in writing. In that case, DQS will assign a replacement for the rejected auditor. This applies to auditors in training/ qualification, too.

3.6 Confidentiality and Information Security

The documents provided to the Client by DQS, including the Marks and the DQS certification symbol, are protected by copyright. Client specifically acknowledges that all documents which are provided or made available by DQS for examination remain the property of DQS, and that they may be used only for the internal needs of Client and not made available to third parties or be used for purposes other than those agreed upon herein or in writing. Client is obliged to maintain strict confidentiality about any information revealed within the terms of this Agreement as well as of all knowledge of matters relating to DQS, its employees and auditors. This obligation also applies after termination of the contract. Client shall not use their certification in any manner that may discredit DQS, nor shall Client issue any statements regarding their certification that the certification administration may regard as being misleading or unjustified. Client similarly accepts this obligation on behalf of any vicarious agents and auxiliary persons. Client is permitted to forward the audit report in its entirety. The forwarding of extracts is not permitted.

3.7 Right to use Certificates and Marks

With a valid DQS certification, the Client is entitled to use the certificate and respective certification marks for promotion purposes. Authorized use of copyrighted DQS Certified Management System Mark and other Certification Marks (herein referred to as the "Marks") shall enhance confidence of customers in the Client's certified management system and the respective performance. These Marks are frequently used on company stationery, in brochures, the Internet, at exhibitions, on vehicles or in advertisements. The Marks are directly associated with the certified organization and its management system or products. Certificates and Marks may be used for promotion in accordance with the provisions of these Auditing and Certification Regulations. Such use is restricted to the scope and the period of validity of the certification. Marks may not be attached directly to a product or used in such a way as to give rise to the impression of being related to the conformity of a product with the standard or specification on which they are based. Section 5, Certificates and Marks, provides respective rules in detail. DQS is obliged to ensure correct use of certificate symbols.

3.8 Appeals and Complaints

Every Client of DQS has the right to have services performed within the agreed scope in such a way that all reasonable expectations and requirements are fulfilled. In case of non-fulfillment, the Client is entitled to file a complaint with the respective DQS Company. DQS will request information necessary for analysis and improvement. In case of a difference of opinion with DQS auditors or a specific certification decision, the Client has the right to submit an appeal to the responsible DQS Company. If a solution cannot be worked out directly with the individuals concerned, Client may make a written appeal for resolution to the Top Management of the contracted DQS Company or, in a last instance, the Board of Arbitration whose decision shall be final.

4. Rights and Obligations of DQS

4.1 Management System Audits

DQS verifies the conformity and effectiveness of

Client's certified management system by performing regular audits in accordance with DIN EN ISO / IEC 17021-1:2015 (at the moment within 12 months). For these audit purposes DQS has the right to access Client's facilities within the framework of planned audits as well as to observe operations, inspect processes, products and services, interview employees and representatives, review documents and pertinent records, and to collect information using other audit techniques and methods. Should DQS receive information from third parties which dispute the conformity or effectiveness of a management system DQS has certified, it is entitled to perform additional, non-routine audits after consulting with Client. In legally regulated areas, DQS is entitled to perform additional, unannounced audits, whenever justified.

4.2 Accreditation and Authorization

DQS is authorized by various accreditation bodies and other Government and Non-Government Authorities to issue audit reports and certificates according to various standards and specifications. This includes the obligation to allow employees or auxiliary persons of these bodies to participate in audits. According to the applicable accreditation and authorization rules, DQS allows these individuals access to both its own documents and Client-related data, subject to the confidentiality requirements set forth herein. In addition, whenever individual standards or specifications explicitly require, Client-related data and audit results are passed on to these bodies. By accepting these Auditing and Certification Regulations the Client consents to the applicable accreditation and authorization requirements, including all of the following. DQS is entitled to assign specific auditing and certification tasks to other DQS Companies holding the required accreditations or authorizations. Whenever certificates are issued by a DQS Company other than the Client's contractual DQS partner, all relevant rights and obligations herein apply equally to both the accredited and the certifying DQS Company.

4.3 Assignment of Auditors

The assignment of competent auditors is the sole responsibility of DQS. DQS agrees to use only auditors who are qualified for the task on the basis of their technical qualification, their experience and their personal abilities. Auditors shall be authorized for the required standard(s) or specification(s) and will have appropriate experience in Client's area of operation as well as in management and auditing. In many cases DQS may assign an audit team, comprised of two or more auditors, to a specific auditing or certification process. On request, DQS will submit a short CV of the selected auditor to the Client. Should an auditor become unavailable before or during the audit, DQS will strive to provide a suitable replacement, if feasible.

4.4 Scheduling Audits

DQS has the right to schedule audits and certifications of the Client's management system. Audits shall be scheduled at the mutual convenience of both parties within the time frames mandated by the applicable requirements. Audit dates shall be agreed upon in writing. Once confirmed, such audit dates are binding. Specific contractual agreements may

include provisions for compensation for canceling or postponing confirmed audits.

4.5 Issuance of certificate

DQS shall issue a DQS Certificate (herein referred to as "Certificate") to Client upon Client's fulfillment of all certification requirements and contractual obligations. The certification decision is the sole responsibility of the accredited and issuing DQS group company, based on the auditor's recommendation for issue and all audit results, as recorded in the audit report. DQS certificates are valid for a limited period of time, usually a maximum of three years, commencing from the date of issuance.

4.6 Confidentiality and Data Protection

DQS commits itself to protect the confidentiality of all confidential information of Client that is not publicly available and that is made available to DQS in the context of its activities on Client's premises, whether this information relates to internal matters of Client or to its business relations. This also applies to the verbal and written results of the audit. DQS will disclose confidential information to third parties only with the written authorization of Client, unless explicitly provided otherwise in these Auditing and Certification Regulations. When statutory provisions require, or contractual obligations permit, disclosure of confidential information, DQS shall notify the Client or the person concerned about it. DQS retains records associated with audits for a minimum of two certification cycles (usually six years). These commitments also apply after termination of the contract.

4.7 Publicity

DQS is entitled to maintain and publish a register of all Clients holding a current DQS certification. This publication contains the name and address of the certified organization as well as the scope and reference standard/specification and certification status. Client hereby consents to the publication of such information hereunder. The publication follows the legal requirements and is up to the discretion of DQS.

4.8 Electronic Communication

Notwithstanding the foregoing, Client hereby authorizes DQS to transmit unencrypted confidential information and other information through the Internet or a public network to e-mail addresses or other locations provided by Client. Client acknowledges that DQS cannot guarantee the privacy and confidentiality of such transmissions. Client agrees that DQS' transmission of confidential information via the Internet or other public network shall not be a breach of any confidentiality obligation under these Auditing and Certification Regulations and that DQS shall not be liable for any damages resulting from such transmissions, provided that such confidential information is handled with the same degree of care as DQS handles its confidential information. If Client hyperlinks to DQS' web site, Client agrees: (i) the information contained on DQS' web site belongs to DQS; (ii) the linking web site will transfer the user directly to DQS' web site as posted by DQS without imposing any frames, browser windows or third-party content; and (iii) the linking web site may not state or imply that Client or its products or services are endorsed by DQS.

5. Certificates and Marks

5.1 Issuance and use of Marks

DQS issues certificates confirming the conformity of the Client's management system to selected national and international standards as well as to recognized industry- or customer-specific requirements, when the Client has demonstrated in an audit that all applicable requirements have been fulfilled. Management system certificates don't confirm compliance with legal requirements. The Client is entitled to use the certificate and the related certification marks to promote confidence with business partners. Upon issuance of a Certificate, an ongoing surveillance service will be established to ensure that conformity of the management system is maintained continuously. The establishment and maintenance of certification is contingent upon the execution of the auditing and certification agreement and the continued adherence to its terms and conditions by the Client. Client agrees to cooperate with DQS in ascertaining the facts if it is reported that Client's management system, processes, goods or services are not in conformance with regulatory, statutory, certification or other applicable requirements, including sharing such information as Client acquires regarding the reported nonconformance, and to take and report to DQS on any corrective action necessary. Client agrees that the surveillance service, such as advancement audits, and any special audits conducted by DQS are designed to serve only as a check on the means the Client exercises to determine conformance of its management system with certification requirements, and that Client is in no way relieved of its responsibility for its management system, processes, goods and services within the scope of certification. Certificates and Certification Marks may not be transferred to successors in title or other organizations. After a certification has expired or has been suspended, withdrawn or annulled, Client must desist from any promotion or other use of the certification. Client agrees to return the certificate following expiration, withdrawal or annulment. The right of retention is specifically excluded. Further information on the Marks is available on the website of DQS MED (www.dqs-med.de).

5.2 Non-issuance of Certificates

DQS may only issue Certificates if all requirements of the selected standard(s), specifications and contracts have been fulfilled following the certification (initial/re-certification). In case of non-fulfillment, the auditor documents the shortcomings in a nonconformity report and/or otherwise identifies the restraints which must be complied with in order for a certificate to be issued. All non-conformances or restraints shall be eliminated prior to the issuance of a DQS certificate. If necessary, DQS will repeat the audit partially or in full. If the non-conformances have not been eliminated or if the prerequisites for the granting of a certificate have not been achieved even after follow-up audits, the certification procedure will be concluded by the issuance of a report without a certificate.

5.3 Suspension, Withdrawal and Annulment of a Certificate

5.3.1 Suspension

DQS is entitled to suspend temporarily a Certificate if Client violates certification,

contractual or financial obligations towards DQS, including but not limited to:

- Corrective actions to the management system have not been demonstrably and effectively implemented within the agreed-upon time frame
- The schedule of audits suggested by DQS for audit(s) necessary for the maintenance of the certification have not been complied with and the prescribed deadline in accordance with 4.1 since the previous audit has thereby been exceeded
- DQS has not been informed in a timely manner about planned changes to the management system and other changes which affect the system's conformity with the standard or specification which forms the basis for the certification
- A DQS certificate, an IQNet certificate or a certification symbol has been used in a misleading or unauthorized manner
- Due payments for auditing and certification services have not been made in time, following at least one written reminder.

DQS will notify Client of a proposed suspension in writing. If the reasons for the proposed suspension are not eliminated within two weeks, DQS will inform Client in writing of the suspension of the Certificate stating the reasons as well as the corrective actions necessary for the certification to be reinstated. Certificates are suspended for a restricted period (usually a maximum of 90 days). If the required measures have been implemented demonstrably and effectively by the established deadline, the suspension of the Certificate is cancelled. If the required measures have not been implemented within the established deadline, DQS may withdraw the Certificate as set forth below.

5.3.2 Withdrawal

DQS is entitled to withdraw Certificates or to declare them invalid upon written notice to Client if:

- The suspension period of the Certificate has been exceeded
- The conformity of the management system with the standard or specification on which it is based is not ensured or Client is not willing or able to eliminate nonconformities
- Client continues to use the certification for promotion following the suspension of the Certificate
- Client uses the certification in such a way as to undermine the reputation of the certification body or DQS
- The preconditions which led to issuing the Certificate no longer apply
- Client files any voluntary or involuntary petition for bankruptcy
- Client effectively terminates its contractual relationship with DQS
- Due payments for auditing and certification services have not been made in time, following at least one written reminder.

5.3.3 Annulment

DQS is entitled to annul Certificates, or retroactively declare them invalid, if:

- It subsequently turns out that the preconditions required for issuance of the Certificate had not in fact been fulfilled
- Client has compromised the certification procedure so that the objectivity, neutrality or independence of the audit results are, in the judgment of DQS, in question

6. Sector-specific requirements

In addition to the provisions stipulated above, specific technical requirements of individual standards or specifications and their complementary interpretations, collectively known as "Program Requirements" are applicable as follows

DQS MED Programs:

General Business Conditions (GBC) of DQS Medizinprodukte GmbH

Supplement to the GBC of DQS Medizinprodukte GmbH applicable for auditing and certification under MDD 93/42/EEC

Supplement to the GBC of DQS Medizinprodukte GmbH applicable for auditing and certification under ISO 13485:2003 under CMDCAS

Supplement to the GBC of DQS Medizinprodukte GmbH applicable for auditing and certification under Medical Device Single Audit Program (MDSAP)

Supplement to the GBC of DQS Medizinprodukte GmbH applicable for auditing and certification under MDR

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