Supplement to the General Business Conditions of DQS Medizinprodukte GmbH applicable for auditing and certification under Medical Device Single Audit Program - valid from January 2022

Specific conditions for the management system auditing and certification services of DQS Medizinprodukte GmbH, hereinafter referred to as “DQS MED”, with its contracting partner, hereinafter referred to as “customer”, applying for auditing and certification under the Medical Device Single Audit Program (MDSAP).

The following provisions apply in addition to the General Business Conditions of DQS MED and DQS Auditing and Certification Regulations. The validity of the remaining provisions of the General Business Conditions of DQS MED and DQS MED Auditing and Certification Regulations remain unaffected.

1. Medical Device Single Audit Program (MDSAP)

DQS MED is an Auditing Organisation recognized under the Medical Device Single Audit Program (MDSAP).

The current statutory regulations, as well as the requirements of the MDSAP apply to the process within the framework of audit and quality management certification under MDSAP. In this process, any applicable requirements of the country-specific regulatory requirements of participating Regulatory Authorities (RAs) are considered as part of audit and certification requirements.

2. Regulatory Authorities (RAs)

The following regulatory agencies act as Regulatory Authorities under the MDSAP:

- Therapeutic Goods Administration of Australia (TGA);
- Brazil’s Agência Nacional de Vigilância Sanitária (ANVISA);
- Health Canada (HC);
- Japan’s Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency (MHLW/PMDA);
- US Food and Drug Administration (FDA).

3. Authorization and Recognition

DQS MED maintains a valid recognition by above-mentioned RAs under the MDSAP and is authorized to provide quality management system auditing and certification services.

Due to its obligations according to rules of authorization and recognition, DQS MED allows employees or auxiliary persons of above-mentioned RAs to participate in audits, so that they can convince themselves of the correct conduct of audits.

Due to its obligations according to rules of authorization and recognition, DQS MED allows above-mentioned RAs to access to both its own documents and customer’s data. This includes any document considered by the RAs as necessary to determine customer’s conformance to the auditing and certification requirements. Such documents would include those that DQS MED and its auditors use to plan, perform, follow up, report observations or report results of an audit, or follow up on a regulatory investigation. The employees of the RAs are sworn to secrecy. Wherever it is explicitly required by the requirements under the MDSAP, customer-related data and audit results are passed on to the RAs. The RAs may share all documents and records related to medical device audits with other regulatory authorities that have formal established confidentiality agreements between governments which cover provisions for protecting proprietary information and trade secret information.

Through the conclusion of an agreement, the customer assents to the possible participation of employees of above-mentioned RAs in the audit of its company, as well as to their access of customer’s quality management and product documentation as relevant for above-mentioned purposes.

If requested, the customer ensures physical access of the RAs to its own facilities and to the facilities of any of its suppliers and subcontractors included in the audit program.

4. Quality management system requirements under MDSAP

The customer must implement and maintain a documented management system which fulfils the requirements of the country-specific requirements of all jurisdictions of above-mentioned participating RAs where the customer markets or intends to market its medical devices, unless the regulations administered by the RAs permit the exclusion.

DQS MED plans, performs, follows up, reports observations or report results of an audit according to the framework of audit and quality management certification under MDSAP in its most current version.

5. Special and unannounced audits under MDSAP

DQS MED utilizes the the Global Harmonization Task Force document, GHTF/SG3/N19:2012, “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange” to determine if a customer is receiving significant or frequent nonconformities or if a nonconformity has resulted in the release of nonconforming medical devices.

DQS MED may carry out unannounced audits if previous audits indicate serious or frequent nonconformities. An unannounced audit shall mandatorily occur following any audit that results in:

- one or more nonconformity(s) graded as a “5”; or
- more than two nonconformities graded as a “4”

Unannounced audits on premises of the client or its contracted critical suppliers may be carried out at any time and shall be foreseen in the contractual arrangements between the customer and its suppliers.

The timing of unannounced audits shall be unpredictable and in addition to normally scheduled audits. In the case of an unannounced audit due to frequent noncompliance or release of nonconforming medical devices, DQS MED will allow approximately 6-9 months for the client to implement their Corrective Action plan, unless the manufacturer has provided evidence that the Corrective Action plan will be completed earlier. These unannounced audits will focus on the noncompliance, and the correction, the corrective action and the systemic corrective action taken for both the client‘s quality management system, as well as any medical devices produced under the nonconformance released to the market or still within the control of the client.

If a visa is required to visit the country where the manufacturer is located, invitation(s) issued by the customer and its critical supplier(s) to visit the customer or contracted critical supplier at any time, with the date of visit left open, shall be provided to DQS MED upon request and renewed periodically.

Should DQS MED receive information from third parties which dispute the conformity or effectiveness of a management system it has certified, it is entitled to perform additional, non-routine assessments after consulting with the customer concerned.

Upon request by an RAs, DQS MED will perform a special or unannounced audit of a customer under the direction of the RAs requesting the special audit.

In the event of above-mentioned special or unannounced audits, the audit team will be selected with particular diligence due to the fact that the customer does not have the opportunity to raise objections against members of the audit team.

Costs occurred in regard to above-mentioned special or unannounced audits are borne by the customer.

6. Information obligations of DQS MED as MDSAP Auditing Organisation

DQS MED complies with the information and reporting requirements for MDSAP Auditing Organisations. This includes reporting to the RAs, including indication of reasons and circumstances as appropriate, of:

- accepting the customer's application for auditing and certification under MDSAP;
- withdrawal of a customer from auditing and certification under MDSAP;
- information about the audits and decision on conformity to quality management system requirements (including audit reports and their attachments);
- becoming aware, without the obligation of establishing objective evidence, of any fraudulent activities or counterfeit products related to the customer;
- all certificates with reductions of scope;
- all suspended certificates;
- all withdrawn certificates;
- information on any complaint (e.g. whistleblowers) that DQS MED receives about the customer that could indicate an issued related to the safety and effectiveness of medical devices or public health risk.

The customer's consent to this is presupposed.

Upon ending its relationship with the customer, or its manufacturing site(s), DQS MED, upon request and with consent of the customer, shall make available to the next Auditing Organisation a copy of all the audit reports from the current certification cycle and a valid certificate of the customer or relevant to the manufacturing site(s).

7. Certification document and use of certification marks

The MDSAP certificate is an attestation that the facilities listed in the certificate have been audited against the listed criteria for the listed scope and found to conform to those requirements, including the regulatory requirements for the specified jurisdictions of the RAs. It does not represent a marketing authorization nor does it oblige above-mentioned RAs to issue any such marketing authorization or endorsement of the customer or its devices

The name of the customer that is to appear on the certification document will be determined by the legal manufacturer based on the jurisdiction in which they market, or plan to market, their products and their legal obligations in relation to registration, listing, or licensing in those jurisdictions.

The certification documents will include the complete civic (physical) address of all audited facilities within the scope of the certification and part of the customer's quality management system. The certification document will include an unique identifier(s) of all audited facilities.

The customer is entitled to use the certification document to demonstrate compliance of its quality management system with requirements of participating Regulatory Authorities (RAs) as considered as part of the audit program and covered by the certification document and to promote confidence with business partners.

The customer commits itself to

- making DQS MED aware of any errors and incorrect or potentially misleading statements on the certification documents to actively prevent misinterpretations thereof;
- adhering to the stipulations of DQS MED regarding reference to the certification status in the communication media and the advertising media;
- refraining from making misleading statements regarding its certification or of allowing such statements to take place;
- refraining from using the certification documents or parts thereof in a misleading manner or of allowing such use to take place;
- changing all promotion Material in the event of the scope of the certification being reduced or restricted;
- not permitting the implicit suggestion that the certification activities have validity beyond the area of their scope;
- not in any way using certification in a way which would bring the certification body or the certification system into disrepute

8. Withdrawal

DQS MED is entitled to withdraw its MDSAP certificates as soon as permanent or unannounced access to the premises of the client or its contracted critical supplier(s) is no longer assured.