Supplement to the General Business Conditions of DQS Medizinprodukte GmbH applicable for auditing and certification under Medical Device Directive 93/42/EEC (MDD) - valid from December 2018

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 “client”, applying for auditing and certification under Medical Device Directive 93/42/EEC (MDD).

The following provisions apply in addition to the General Business Conditions of DQS Medizinprodukte GmbH. The validity of the remaining provisions of the General Business Conditions of DQS Medizinprodukte GmbH remains unaffected.

1. Directive 93/42/EEC concerning medical devices

DQS MED is a notified body for the Directive 93/42/EEC concerning medical devices (identification number: 0297). The current statutory regulations as well as the rules for designation of notified bodies apply to the process within the framework of the Directive 93/42/EEC.

2. Assessment

a) Review of product documentation

DQS MED reviews the product documentation in accordance with the Directive 93/42/EEC with the aim of establishing the fulfilment of the Essential Requirements of the Directive 93/42/EEC for the product as well as establishing the fulfilment of the documentation requirements of the manufacturer. During the review process, both technical and clinical experts will be involved in the task of reviewing the compliance with the underlying specifications and standards. In case of a positive certification decision, the client receives a DQS MED certificate or an extension of its existing certificate. In case of the process according to the Directive 93/42/EEC Annex II.4, the client receives an assessment report about the conclusion of the review process as well as a separate certificate about the EC design examination according to Annex II.4. During the review, DQS MED is independent, neutral and objective and ensures that the assigned experts are also independent, neutral and objective at the review and adhere to strict confidentiality with regard to information acquired in the context of the review process.

If the product contains a pharmaceutical in terms of the Directive 2001/83/EC, DQS MED will initiate the consultation process with a competent authority as required for this purpose.

If the product has been manufactured utilising tissues of animal origin, falling under the Regulation 722/2012/EG, competent authorities will be requested to provide statements. These statements shall be taken into account by DQS MED in the decision process.

The documents requested for review must be made available to DQS MED either in English or in German.

b) Selection of assessors

The number and selection of assessors resides with DQS MED. DQS MED nominates the assessor(s) and provides the client with their professional profile. DQS MED commits itself to assign only assessors who are suitable for the task on the basis of their technical qualifications, their experience and their personal abilities. They are authorized assessors for the underlying standards or specifications and have appropriate experience in the client’s area of operation as well as in management and auditing.

The client is entitled to reject the assessor(s) proposed by DQS MED with appropriate written justification. In such cases, DQS MED will name a replacement for the rejected assessor. This also applies to auditors in the training/qualification. Should an assessor become unavailable immediately before or during the assessment, the two parties shall mutually agree on how to proceed. The procedure in accordance with 3 and 4 remains unaffected hereby.

3. Effectiveness of certified management system

DQS MED verifies the effectiveness of the client’s certified management system by performing regular assessments.

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 at short notice by informing the client. For processes which come under the Directive 93/42/EEC, DQS MED has the right to perform additional unannounced audits. In the event of assessments for extraordinary reasons and also for unannounced audits, the audit team will be selected with particular diligence due to the fact that the client does not have the opportunity to raise objections against members of the audit team. Costs occurred hereby are borne by the client.

4. Independence of the assessment

The client is obliged to ensure the independence and impartiality of the DQS MED assessments and certifications in relation to the client prior to receiving these services and to refrain from anything that could affect the independence and impartiality of the DQS MED staff and assessors. This applies in particular to offers of consultancy work, of employment and commissions, both salaried and freelance, to separate agreements regarding fees or other monetary benefits. Should the client become aware of circumstances that compromise, have compromised or could compromise the independence and impartiality of a DQS MED assessment, he is obliged to inform DQS MED about this immediately. DQS MED is obliged to exclude all DQS MED employees and assessors from the certification process in the event that their independence and impartiality are not ensured. The DQS MED Policy on Independence and Impartiality is provided to the client on request.

5. Information obligations of DQS MED as notified body

As notified body for the Directive 93/42/EEC, DQS MED complies with the reporting obligation provisions of § 18(3) and § 36 of the German Medical Devices Act, “Gesetz über Medizinprodukte”. This includes reporting on:

- all issued and amended certificates;
- all declined certifications, with indication of reasons;
- all certificates with extensions and reductions of scope;
- all suspended and reinstated certificates;
- all withdrawn certificates.

The client’s consent to this is presupposed.

6. Certificates and certification symbols

a) Issuance and use

DQS MED is obliged to issue a certificate and deliver it up to the client upon fulfilment of all certification requirements and contractual obligations. The certification decision is the sole responsibility of DQS MED, and is based on the assessor’s recommendation as recorded in the assessment report. DQS MED certificates in accordance with 93/42/EEC have a validity period of five years commencing at the earliest from the date of establishing the conformity by way of certification decision.

Such use is restricted to the scope and the period of validity of the certification. In referring to the certification and in using the certificate symbol, no ambiguity should exist in the conformity symbol or accompanying text regarding what has been certified. DQS MED is obliged within the framework of its possibilities to ensure that correct use is observed. The client commits itself to,

- 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 and/or the certification system into disrepute.

b) Use of the CE-mark

The legal specifications for marking a product (CE mark) are to be adhered to by the client.

c) Extension of scope

Should changes occur during the period of validity of a certification, which make it necessary to extend the scope of certificate (e.g., new sites, lines of production and activities), the scope can be extended, if applied for by the client.
The precondition for the extension of scope is the assessment of the effectiveness of the extended quality management system with respect to the specifications of the underlying standard.

d) Reduction of scope

DQS MED is entitled to reduce the scope of the issued certificate in the event that the customer has evidently breached its obligations, especially where,
a) corrective actions to the management system with regard to the respective part of the certification scope have not been evidently and effectively implemented within the agreed timeframe;
b) DQS MED has not been immediately informed of changes to the management system and other changes which would influence the management system's conformity to the underlying standard;
c) the preconditions with regard to respective part of the certification scope which led to the issuance of the certificate no longer exist.
Prior to the decision to reduce the scope of certification, the customer will be listened to by DQS MED, unless such a hearing is not possible due to the urgency of the decision to be made.
Initially, the reduction of scope of certification is limited in time. If the necessary corrective actions are evidently and effectively implemented within the time limit set, then the reduction of scope of certification will be rescinded.
After the reduction of the scope of the certification, the customer must immediately cease to use the certificate with regard to the parts which no longer apply and refrain from such use during the whole period of the limited restriction. Subsequent to a final reduction of scope (i.e. beyond the time limit set), the certificate with the reduced scope will be correspondingly revised.
DQS MED is not liable for costs incurred for the customer due to the reduction of certification scope or its consequences.

e) Suspension

DQS MED is entitled to suspend a certificate for a limited period of time if the customer evidently violates contractual or financial obligations towards DQS MED, especially if:
a) corrective actions to the management system have not been evidently and ef-fectively implemented within the agreed timeframe;
b) the dates proposed by DQS MED for the assessment necessary for the mainte-nance of the certification or for the re-certification cannot be complied with and, consequently, the time limit of twelve months is being exceeded;
c) DQS MED has not been informed imme-diately about changes to the management system and other changes which affect the system's conformity to the underlying standard or specification;
d) a DQS MED certificate or a certificate symbol was used in a misleading way;
e) the financial obligations agreed to with DQS MED have not been fulfilled;
f) the conditions which led to the issuance of the certificate no longer exist;
g) the customer does not fulfill his duties of disclosure.
Prior to the decision regarding suspension, the customer will be listened to by DQS MED,
unless such a hearing is not possible due to the urgency of the decision to be made. The suspension of certification is limited in time. If the required measures have been evidently and effectively implemented by the fixed deadline, the certification will be reinstated.
Subsequent to the suspension of a certification, the customer must immediately cease to use the certificate and refrain from such use for the whole period of the suspension. DQS MED is not liable for costs incurred for the customer due to suspension of the certificate or its consequences.

f) Withdrawal

DQS MED is entitled to withdraw certificates if:

- the conformity of the management system with the underlying standard is not ensured;
- the certified product is no longer covered by the scope of the Directive 93/42/EEC;
- the medical device has been assigned a different class;
- the medical device no longer fulfils the essential requirements of the Directive 93/42/EEC to such an extent that patients, users or other persons are exposed to considerable risks,
- the intended use of the medical device defined by the manufacturer is not fulfilled and that shortcomings have not been eliminated within the scheduled and appropriate time limit;
- contractual obligations are not met on the applicants side. This concerns in particular, however is not limited to, the obligation to inform the competent authorities and DQS MED of any incidents related to medical devices.

Prior to the decision regarding withdrawal, the client will be consulted by DQS MED, unless such a hearing is not possible due to the urgency of the decision to be made. After the withdrawal of certification, the client has to immediately and irrevocably cease to use the certificate. DQS MED is not liable for costs incurred by the client owing to the withdrawal of the certificate and its consequences.