General Business Conditions
of DQS Medizinprodukte GmbH - valid from January 2014

General business conditions and special terms and conditions for the assessment of management systems of DQS Medizinprodukte GmbH, hereinafter referred to as “DQS MED”, with its contracting partner, hereinafter referred to as “customer”.

1. Scope

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” and auditors and experts as “assessors”, audit and assessment reports are referred to as “assessment reports” The certification documents are referred to as “certificates”.

1.1. 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

2.1. Assessment of management systems

DQS MED assesses its customer’s management system, or part thereof, with the aim of determining its conformity with agreed requirements including the effectiveness of the management system.
Provided it is specified in the relevant standard, the review and the assessment of the effectiveness of the quality management system also extends to the documents, processes and other issues specific to the product. The customer receives an assessment report and a DQS MED certificate. DQS MED is independent, neutral and objective in its assessments. Management system audits are performed at the customer’s place of operations. The customer’s suppliers and subcontractors shall also be included in the assessment, if this is necessary due to requirements for certification of the customer. The type, scope and schedule for the process are agreed to separately by both parties. Should nonconformities to the requirements of the underlying standard or specification be identified during an assessment, the corrective actions must be evidently implemented by the customer within the time frame specified by the DQS MED process, and/or the predetermined underlying standard or regulation, and/or by an appropriately agreed deadline, before a DQS MED certificate can be issued.

2.2. 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 customer receives a DQS MED certificate or an extension of scope of its existing certificate. In case of the process according to the Directive 93/42/EEC Annex II.4, the customer 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 medicinal product 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.

3. Selection of assessor

The number and selection of assessors is incumbent upon DQS MED. DQS MED nominates the assessor(s) and provides the customer 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 customer’s area of operation as well as in management and auditing.
The customer is entitled to reject the assessor(s) proposed by DQS MED without specifying any reasons. In that event, DQS MED will submit a new proposal. The entitlement to reject assessors may be exercised only once at the beginning of both the preparatory and the surveillance phase. 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 4.6 and 5.5 remains unaffected hereby.

4. Rights and obligations of DQS MED

4.1. Confidentiality and data protection

DQS MED commits itself to confidentiality regarding all the affairs of the customer which have become known in the context of its activities at the customer’s premises or through notification from third parties, e.g. claimants or regulators, regardless whether it refers to internal matters pertaining to the customer himself or its business connections. This also applies to the verbal and written results of the assessment. DQS MED only passes information to third parties on the basis of written authorization from the customer. Information and obligation to inform in accordance with 4.2, 4.5 and 4.8 remain hereby unaffected. DQS MED retains records concerning assessments, evaluations and decisions for at least 17 years. These commitments also apply after termination of the contract. DQS MED operates a secure web portal on its website which allows access to assessment results and other information. Customers may only enter this web portal after having received authorization (log-in data and password) and on submission of electronic or written consent.

4.2. Accreditation and authorisation

DQS MED is authorised by various accreditation bodies and authorities to issue assessment reports and certificates according to various standards and specifications.
Due to its obligations according to rules of accreditation, designation and recognition, DQS MED allows employees or auxiliary persons of these bodies and authorities to participate in assessments, so that they can convince themselves of the correct conduct of assessments.
In so far as this is essential for accreditation procedures, DQS MED allows these bodies and authorities access to both its own documents and customer’s data. The employees of these bodies and authorities are sworn to secrecy. Wherever individual standards or specifications explicitly require it, customer-related data and assessment results are passed on to these bodies and authorities.
Through the conclusion of an agreement, the customer assents to the possible participation of employees from the accreditation bodies and the competent regulators in the assessment in his company, as well as to their access of customer’s product documentation. The customer ensures physical access of these bodies and authorities to its own facilities and to the facilities of any of its suppliers and subcontractors included in the assessment.

4.3. Liability and limitation of liability

DQS MED may be held liable only in case of intent and gross negligence. This also applies to its vicarious agents and auxiliary persons. Upon request, DQS MED will provide evidence of liability insurance for contracted services.
Should DQS MED’s liability come into consideration, it shall be limited to a maximum of € 100.000,- per business transaction and € 250.000,- per calendar year.

4.4. Release from liability

The customer releases DQS MED from any claims of third parties resulting from the review of technical product documentation provided by the customer.

4.5. Publication

DQS MED maintains and publishes a register of all customers holding a current DQS MED certification.
The publication contains the name and address of the certified organisation, the underlying standard or specification, the scope and geographic location, or respectively, the geographic locations within the scope of a multiple site certification, as well as the electronic version of

the valid certificate. On the request of a third party, the validity of a specific certification will be confirmed, or respectively, information regarding declined certification, suspension, alteration, extension of scope, reduction of scope, or withdrawal of a certificate will be imparted. The customer's consent to this is presupposed.

4.6. Effectiveness of certified management systems

DQS MED verifies the effectiveness of the customer'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 after consulting with the customer concerned. 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 extra-ordinary reasons and also for 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 hereby are borne by the customer.

4.7. Scheduling appointments

DQS MED and the customer schedule appointments as far in advance as possible. Appointments are confirmed in written form. In the event that a confirmed appointment cannot be maintained by reason of the customer, DQS MED may charge the customer for actually incurred expenditures in preparing for this appointment.

4.8. 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 (7.1);
- all declined certifications, with indication of reasons (7.2);
- all certificates with extensions and reductions of scope (7.4 and 7.5);
- all suspended and reinstated certificates (7.6);
- all withdrawn certificates (7.7).

The customer's consent to this is presupposed.

4.9. Notification of changes

DQS MED informs the certified customer on time about all changes regarding its certification requirements.

5. Rights and obligations of the customer

5.1. Management system

The customer must implement and maintain a documented management system which fulfils the requirements of the underlying standard or specification. All actions necessary to ensure the stability and effectiveness of the management system must be carried out and documented.

5.2. Duty of disclosure

The customer ensures that DQS MED has access to all necessary information and the requisite facilities to fulfil its task, and commits all nominated representatives and employees to provide the assessor in a timely manner with accurate and complete information concerning all processes which may be of significance to the assessment. Within the scope of certified management systems, all records relating to complaints and their corrective actions must be presented to DQS MED upon request.

5.3. Notification of changes

The customer is obliged to inform DQS MED forthwith of any changes which may influence the certified management system or other changes which may affect the underlying standard. This applies in particular to changes in the legal form or organisational form; the economic or ownership conditions, e.g. purchase/sale of parts of the company, or change in ownership; address and location changes; changes in structure and management, e.g. changes in key personnel, decision making or specialised staff ; changes in the recorded area of activities of the certified management system; changes in product portfolio, changes to products, and fundamental changes of the management system and the processes as well as the opening of insolvency, composition and bankruptcy proceedings.
In any of these cases, DQS MED will consult with the customer and examine how the certificate may be maintained.

5.4. Confidentiality and secrecy

The customer is permitted to pass on the assessment report in its entirety. Forwarding of extracts is not permitted. The documents provided to the customer by DQS MED, including the DQS MED certification symbol, are protected by copyright. The customer explicitly acknowledges that all documents which are provided or made available by DQS MED for review remain the property of DQS MED, and that they will be used only for the needs of the company and not made available to third parties or used for purposes other than those agreed upon. The customer 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 MED, its employees and assessors. This obligation also applies after termination of the contract. The customer similarly accepts this obligation on behalf of any vicarious agents and auxiliary persons.

5.5. Independence of the assessment

The customer commits itself to convincing itself of the independence and impartiality of assessments and certifications in relation to the customer in advance of availing of DQS MED services, and also of refraining from anything which might compromise the independence of DQS MED employees and assessors. This applies in particular to offers of consultancy work, of employment and commissions both salaried and free-lance, to separate agreements regarding fees or other monetary rewards. Should the customer become aware of circumstances that can compromise, have compromised or could compromise the independence and impartiality of a DQS MED assessment, it is obliged to inform DQS MED about this immediately.

DQS MED commits itself 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 will be made available to the customer on request.

6. Services, prices and conditions of payment

The customer acknowledges DQS MED's General Business Conditions and prices in their current versions, unless stipulated otherwise in a contract. Invoices will be issued following each stage of performance of services and are due for payment in full within ten days from the date of the invoice, without deductions. In the event of delayed payment, DQS MED is entitled to charge interest at the current bank rate.
Offsetting of not recognized claims by DQS MED or not legally binding claims of the customer is excluded.

7. Certificates and certification symbols

7.1. Issuance and use

DQS MED is obliged to issue a certificate and deliver it up to the customer 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. Depending on the respective underlying standard, DQS MED certificates have a validity period of three or five years commencing at the earliest from the date of establishing the conformity by way of certification decision. Certificates and certificate symbols may be used for advertisement. 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. The customer restricts such references explicitly to the scope of the existing certification. Certificate symbols may not be directly attached to a product, laboratory testing reports, calibration certificates and inspection reports. In addition, they may not be arbitrarily used in any other way which would give the impression that they refer to the conformity of a product with the underlying standard. DQS MED is obliged within the framework of its possibilities to ensure that correct use is observed. The customer commits itself to,

a) adhering to the stipulations of DQS MED regarding reference to the certification status in the communication media and the advertising media;
b) refraining from making misleading statements regarding its certification or of allowing such statements to take place;
c) refraining from using the certification documents or parts thereof in a misleading manner or of allowing such use to take place;
d) changing all promotion material in the event of the scope of the certification being reduced or restricted;
e) not permitting reference to his management system which could by implication suggest that the certification body has certified a product, a service or a process;
f) not permitting the implicit suggestion that the certification activities have validity beyond the area of their scope;

g) not in any way using certification in a way which would bring the certification body and/or the certification system into disrepute.

Certificates and certificate symbols may not be transferred to legal successors or other organisations. After suspension or withdrawal of a certification, the customer must immediately discontinue all advertising with the certification. The customer undertakes to return the certificate on its withdrawal. A right of retention is excluded. Copying of, or alterations to, the DQS MED certificates may only be carried out by persons who have been authorised to do so by DQS MED.

7.1.1. Use of the CE mark

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

7.2. Declined certification

Standards and specifications requirements must be proven and effectively fulfilled before the certification can be carried out. DQS MED can only issue certificates when subsequent to the assessment (initial or re-assessment) these pre-requisites have been complied with. In the event of non-conformity the assessor documents the deficits in his nonconformity report or announces the conditions that are to be fulfilled for the issuing of a certificate. Non-conformities or restraints are to be remedied within three months. If necessary, DQS MED will fully or partially repeat the assessment. The resulting costs will be invoiced corresponding to the current price list reflecting the actually produced volume of work (person-days etc.). Should the nonconformities not be remedied within three months, or, should the basis for issuing a certificate not be met after two follow-up assessments, the certification will be declined and the certification process will be concluded by a report and without issuance of a certificate.

7.3 Maintenance

At least once within a twelve month period there will be an assessment for the purpose of maintaining the certification. Should it be determined during this assessment that requirements of the underlying standard have not been fulfilled, corrective actions are to be evidently implemented so that the certification can be maintained. The corrective actions are to be implemented in accordance with DQS MED processes and/or in compliance with the specification of the standard within an appropriately agreed timeframe which, however, does not exceed a period of three months.
Prior to the expiration of the certification validity, a re-assessment will be carried out. The same conditions apply to the renewal of the certificate as those applying to the issuance of the certificate.

7.4. 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 customer.
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.

7.5. 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 (see also 7.3);
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 (also see 5.3);
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.

7.6. 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 effectively implemented within the agreed timeframe (see also 7.3);
b) the dates proposed by DQS MED for the assessment necessary for the maintenance of the certification or for the re-certification cannot be complied with and, consequently, the time limit of twelve months is being exceeded (see also 7.3.);
c) DQS MED has not been informed immediately about changes to the management system and other changes which affect the system's conformity to the underlying standard or specification (see also 5.3);
d) a DQS MED certificate or a certificate symbol was used in a misleading way (see also 7.1);
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 (see also 5.2).

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.

7.7. Withdrawal

DQS MED is entitled to withdraw certificates if:

a) the period of suspension of the respective certificate has been exceeded;
b) the customer continues to use the certificate for advertising or for other reasons, following the suspension of the certificate;
c) the customer uses the certification in such a way as to undermine the reputation of the certification body;
d) the preconditions which led to issuing the certificate no longer apply, or the customer is not prepared to eliminate nonconformities;
e) the customer effectively terminates the contractual relationship with DQS MED;
f) the conformity of the management system with the underlying standard is not ensured;
g) the certified product is no longer covered by scope of the Directive 93/42/EEC;
h) the medical device has been assigned a different class;
i) 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,
j) that 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;
k) 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 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.
After the withdrawal of certification, the customer has to immediately and irrevocably cease to use the certificate.
DQS MED is not liable for costs incurred for the customer due to the withdrawal of the certificate or its consequences.

8. Appeals and complaints

Every customer has the right to have services performed in such a way that expectations and requirements are fulfilled within the agreed scope. In case of non-fulfilment, DQS MED requests information necessary for improvements. In case of a difference of opinions with assessors or with DQS MED itself, each customer has the right to submit a complaint, or, against a decision – an appeal. Complaints may be expressed verbally or in writing to any DQS MED employee. Appeals can only be expressed in writing. If a solution cannot be

worked out with the individuals concerned, or the Quality Management Representative of DQS MED, or the Managing Director, than the DQS MED Board of Arbitration may be invoked in writing. The procedure of DQS MED for processing complaints and appeals will be made available to the customer on request.

9. Board of Arbitration

The DQS MED Board of Arbitration may be invoked in the event of complaints and in the event of appeals against decisions on the evaluations, on the issue, reduction of scope, suspension or withdrawal of a certificate. The prerequisite is agreement by both parties to have the matter in dispute resolved without resorting to legal action, along with a jointly-prepared presentation of the situation in writing (arbitration agreement). The Board of Arbitration consists of three individuals. The two parties nominate one arbitrator each. The umpire is nominated jointly by the two arbitrators and must have the qualification for judgeship according to German law. The Board of Arbitration may be invoked by written application to the Executive Council of DQS MED. The full particulars are governed by DQS MED's rules of procedure for the Board of Arbitration (Rules of Arbitration).

10. Duration and termination

The agreement is concluded on the date of placing the order for the duration of one certification cycle. The customer may terminate the agreement in writing with a notice period of one month in advance without stipulating any particular reason. In the event of termination by the customer, DQS MED reserves the right to charge for services already provided. DQS MED may only terminate on important grounds, especially in the case of contravention of provisions of sections 4.2, 5, 6 and 7.

11. Place of jurisdiction and applicable laws

The place of jurisdiction is Frankfurt am Main. The German law applies.

12. Diverging agreements

Diverging or supplementary agreements have to be made in writing. Should any individual provision of the contractual agreements – including those of the General Business Conditions – become ineffective, the validity of the remaining provisions hereof shall not in any way be affected. In such cases, the parties will replace the ineffective provisions immediately coming as close as possible to the sense and purpose of the provisions of the original agreement.

13. Additional provisions

In addition to the provisions stipulated above, specific requirements for particular individual standards apply in their current respective versions including their supplemental interpretations.