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General Order and Payment Conditions

1. General

1.1 MEDCERT is engaged in the business of auditing and certifying medical devices and quality management systems in accordance with recognized standards, regulations and statutory provisions and their guidelines.

1.2 The Customer acknowledges the "Procedure for the Certification and Conformity Assessment of Medical Devices and Quality Management Systems", MEDCERT's "General Order and Payment Conditions" as well as the "Price List" in their current versions.

1.3 Where MEDCERT decides to cease its certification and/or conformity assessment activities, MEDCERT will inform the Customer as soon as possible and in case of a planned cessation one year before ceasing the activities.

1.4 In case MEDCERT's accreditation, recognition or designation has been suspended, restricted, or fully or partially withdrawn, MEDCERT will inform the Customer at least within 10 days.

2. Quotations

Quotations always relate to the information available at the time of preparation. Cost estimates shall be regarded as price recommendations. Orders placed without having received a quotation shall be charged at cost and in line with the price list in its current version.

3. Order Execution

3.1 Orders accepted by MEDCERT shall be executed in accordance with recognized standards, regulations and statutory provisions and their guidelines valid at the time of order execution.

3.2 MEDCERT shall not assume any warranty for the correctness of the standards, regulations and statutory provisions and their guidelines, unless explicitly otherwise agreed upon.

3.3 The Customer shall submit to MEDCERT in due time all necessary documents such as the documentation on the quality management system and product documentation, incl. drawings, post-market clinical follow-up ("PMCF") and post-market surveillance ("PMS") plans, design results, qualification records of personnel, test samples, calculations and certificates and shall at any time provide any order-related information in order to make the necessary preparations prior to inspections, audits or reviews. All documents as well as any correspondence must be either in German or in English. The Customer bears the sole responsibility for accuracy and authenticity of the submitted documents. The Customer assures MEDCERT that the submitted documents refer to the existing product and/or quality management system. Otherwise, MEDCERT shall be entitled to withdraw from the contract.

3.4 MEDCERT shall be entitled to make copies of any documents to be made available to it, which are necessary for the execution of the order and file such copies in its own records.

3.5 The Customer shall ensure that the medical devices and/or the quality management system always conform with the current certifications. The Customer must immediately inform MEDCERT in writing of a) any serious incident involving devices made available on the Union market (except side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting) and b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field corrective action is not limited to the device made available in the third country.

3.6 The Customer shall inform MEDCERT and submit for prior approval plans and documents for any substantial change (e. g. change of legal, commercial, organizational status or ownership, change of key personnel, decision-making or technical staff, change of contact address and sites, transfer of the production to another location or company or company owner, change of critical supplier, economic operator, change of scope of operation under the certified quality management

system, the product-range covered, the approved design of a device, the intended use of or claims made for the device, the approved type of a device, any substance incorporated in or utilised for the manufacturing utilising tissues or cells of animal origin or their derivatives, and other major changes to the quality management system and processes or any other change which may affect the scope of the certificate) in his quality management system and/or certified products.

3.7 The Customer shall support MEDCERT in the certification and surveillance of the medical devices and/or quality management system. Customer shall allow employees or agents of the recognizing and designating authorities and accreditation bodies to carry out observed audits, short notice, unannounced or “for-cause” reviews in all of Customer’s facilities as well as those of their critical subcontractors or crucial suppliers, if requested and necessary.

3.8 The assessment process includes an assessment of the technical documentation for the relevant product(s), an inspection of the Customer’s facilities and, if sufficient reasons exist, the facilities of critical subcontractors or crucial suppliers. The Customer must contractually ensure that MEDCERT shall receive access to the premises of the respective company premises with its essential critical subcontractors or crucial suppliers. As part of these activities, the Customer shall ensure that all documents, information, inspections and evaluations are submitted as requested by MEDCERT.

3.9 Certification and surveillance involves the assessment of technical documentations of the generic device group (class IIb) and categories of devices (class IIa) for compliance with the requirements specified by the Medical Device Regulation (EU) 2017/745.

3.10 MEDCERT shall, for its own purposes, store data concerning the business correspondence with the Customer in a data processing system. Personal data shall be processed exclusively for MEDCERT's own purposes. In order to fulfil the requirements set forth in the Annex to Section 9 of the Federal Data Protection Act, MEDCERT has taken technical-organizational measures, which warrant the security of data and data processing operations security. The employees entrusted with the processing of data are bound to the Federal Data Protection Act and are obliged to observe any data protection regulation. The Customer is aware that their data is electronically recorded, stored and processed for order processing and order management purposes. The Customer consents to this recording, storage and processing as part of the order processing in accordance with Sections 4, 4a of the Federal Data Protection Act.

3.11 MEDCERT, its employees and any external auditors/experts under contract with MEDCERT are, without prior authorization, not be entitled to use or disclose business and trade secrets towards third parties of which they become aware during the execution of their work.

3.12 MEDCERT shall be entitled to have its services partly rendered by subcontractors carefully selected and regarded as qualified by MEDCERT following prior approval by the Customer.

3.13 MEDCERT respects the confidentiality information and data obtained in order to protect personal data, confidential commercial information, trade secrets and intellectual properties, unless disclosure is in the public interest. This shall not affect the rights and obligation with regard to exchange of information and the dissemination of warnings, nor the obligation concerned to provide information under criminal law.

3.14 MEDCERT shall reserve the copyright to the inspection results, reports, certificates, expert’s opinions etc. compiled and drawn up by it.

3.15 Upon announcement of fixed dates for upcoming audits, MEDCERT shall not assume any legal responsibility to comply with these fixed dates as applicable for the Customer.

4. Scope of Order

4.1 The type and scope of the services to be rendered by MEDCERT shall be clearly specified in writing by the Customer at the time of application. The order cannot automatically be connected to a specific assessment, inspection or certification result.

4.2 Extensions of or amendments to orders already completed shall also be agreed upon in writing prior to their execution. If the parties fail to come to such an agreement, the Customer shall be entitled to terminate the original contractual relationship. In such cases, MEDCERT's remuneration shall be subject to the statutory provisions.

4.3 Usual assistance by parties placing orders or third parties shall be put at MEDCERT's disposal without charge and in due time without the necessity to agree upon it in writing. When providing assistance the Customer shall observe the applicable statutory and administrative regulations.

4.4 Partial services rendered by MEDCERT on the basis of an order and which form an own unit and can be used by the Customer, shall be accepted by the Customer and paid for against a separate invoice.

5. Order Execution Periods · Fixed Dates

5.1 Order execution periods or fixed dates shall only be binding if they have been explicitly designated as such in writing.

5.2 If fixed dates are defined between the both parties, the parties are obliged to promptly submit and deliver their necessary requirements to comply with the fixed date. This is particularly, but not exclusively, applicable for documents and preliminary work that

the Customer is obliged to deliver to MEDCERT in order to comply with fixed dates.

5.3 Binding fixed dates shall only apply if all duties arising from section 3.3 have been complied with in full and in due time.

5.4 Fixed dates shall be extended or postponed as appropriate, or new fixed dates shall be agreed if MEDCERT fails to render its services in due time through no fault of its own. This particularly applies if the Customer is not able to meet an obligation relating to the timely provision of documents or other preliminary work important for MEDCERT's activities. This also applies during the delay in performance of the services.

6. Suspension, cancellation, withdrawal, restriction and refusal to issue certificates

6.1 MEDCERT is entitled to suspend or withdraw certificates, restrict issued certificates or refuse to issue certificates based on recognized standards, regulations, statutory provisions and their guidelines or if significant requirements specified at the time of certification are no longer satisfied. A refusal refers to the refusal to issue a certificate.

6.2 The restriction specified in section 6.1 is related to parts of products covered by a certificate or areas, locations and activities described in a certificate. The products covered by the restriction of certificates in accordance with the Medical Device Regulation (EU) 2017/745 may not be placed on the market with a CE mark.

6.3 The refusal, expiration, withdrawal, restriction, cancellation and suspension of a certificate may be published.

6.4 MEDCERT may reach corresponding decisions if, for instance, one of the following circumstances had already been in place at the time the certificate was issued:

- the requirements from the Medical Device Regulation (EU) 2017/745 required for the issuance of certificate of the quality management system or medical device were not satisfied,
- the product or product category specified in the certificate had been incorrectly assigned to a medical device,
- the medical device or the medical device category had been assigned to a lower class and an incorrect declaration had been issued,

6.5 MEDCERT may also take corresponding actions if, for instance, one of the following circumstances has occurred after the certificate has been issued:

- the statutory requirements for the quality management system, medical device or medical device category approved with the certification are no longer satisfied,
- the product or product category is not, or no longer, covered by the Medical Device (EU) Regulation 2017/745,
- the medical device or medical device category is assigned to a lower class,
- the medical device or the medical device category no longer satisfies the requirements such that patients, users or third parties are exposed to significant risks, or the medical device does not satisfy the intended purpose indicated by the manufacturer and these defects cannot be removed within a prescribed and appropriate period of time,
- the Customer fails to meet deadlines for correction of major nonconformities and/or requirements,
- the Customer does not comply with their payment requirements to MEDCERT.

6.6 Prior to taking any decision in cases described under sections 6.4 and 6.5, MEDCERT shall provide the Customer with an opportunity to present the Customer's view in a hearing, unless there is an urgent reason for MEDCERT to take an immediate decision precluding such a hearing. MEDCERT shall inform the Customer of the decision and specify any required measures. MEDCERT is subject to the duty of reporting and shall forward any relevant status changes to certificates, including and if applicable an assessment of the risk potential of the affected product(s), to the specified bodies/authorities. The Customer is obliged to implement the measures specified by MEDCERT and must demonstrate the implementation of the measures to MEDCERT.

7. Warranty

7.1 MEDCERT's liability for material defects shall - within the framework of a contract for work and services - be restricted to subsequent fulfilment. If this subsequent fulfilment does not take place or fails, the Customer shall be entitled to a reduction of the remuneration (diminution) or a withdrawal from the contract (withdrawal) irrespective of the right arising from Section 637 of the German Civil Code.

7.2 Claims, if any, of the Customer with respect to material defects shall become statute-barred 1 year after the acceptance of MEDCERT's services by the Customer unless the defect has been concealed fraudulently or intentionally caused by MEDCERT.

7.3 The statutory regulations apply in all other respects.

8. Liability

8.1 MEDCERT shall assume maximum liability of 2,0 million Euro if damages are caused as a result of intent or gross negligence. MEDCERT is also liable for the slightly negligent breach of key duties (duties whose infringement threatens the achievement of the contractual purpose) as well as for a breach of cardinal duties (duties whose fulfilment the customer can regularly rely upon); however, only for foreseeable damages typical for the contract in each case. MEDCERT is not liable for the slightly negligent breach of duties not mentioned above.

8.2 The limitations of liability in the above paragraph do not apply in the event of the loss of life, physical injury and damage to health, for a defect after providing a guarantee for the quality of the device and in the event of fraudulently concealed defects. Liability in accordance with the Product Liability Act remains unaffected.

8.3 If MEDCERT's liability is excluded or limited, this also applies for the personal liability of employees, representatives or agents.

9. Remuneration

9.1 Unless explicitly agreed upon otherwise in writing MEDCERT's "Price List" in its current version shall apply.

9.2 As far as "fixed prices" have been agreed upon explicitly in writing such prices shall apply irrespective of the time of service rendering. The Customer shall bear responsibility for any additional expenses that arise due to activities having to be repeated or postponed as a result of delayed, incorrect or incomplete information, or non-compliant duties to cooperate. MEDCERT is also entitled to invoice for these additional expenses if a fixed price has been agreed.

9.3 The amount of statutory value added tax valid at the time being shall be identified separately in the invoice and in addition to the fees.

10. Terms of Payment

10.1 The receipt of an invoice does not automatically mean that MEDCERT has provided a bill for the entire order.

10.2 The fee shall be due for payment no later than the date printed on the invoice.

10.3 In the case of orders lasting longer than one month as well as in case of completed partial services, interim invoices may be issued.

10.4 MEDCERT shall be entitled to request advance payments, if necessary.

10.5 In the event of a default of payment by the Customer, MEDCERT shall charge default interest of 8% per annum above the base rate.

10.6 The statutory provisions shall apply in all other respects in the event of a default of payment and in relation to an appropriate grace period.

11. Place of Fulfilment · Place of Jurisdiction · Applicable Law

11.1 If the Customer is a businessman, legal person governed by public law or a special fund under public law, the exclusive place of jurisdiction for all disputes from this contract is the place of business of MEDCERT in Hamburg. The same applies if the Customer does not have a general place of jurisdiction in the Federal Republic of Germany, or if the place of residence or usual residence is unknown at the time of commencement of proceedings.

11.2 All disputes from this legal relationship are subject to the law of the Federal Republic of Germany. The UN Convention of Contracts for the International Sale of Goods does not apply.

12. Severability and written form requirement

12.1 The full or partial invalidity of individual provisions of this agreement between the Customer and MEDCERT or of the General Order and Payment Conditions shall not affect the validity of other provisions. The Parties are mutually obligated to replace invalid provisions with permissible provisions that fulfil the original financial intent to the closest possible extent.

12.2 Amendments and supplements to this contract must be made in writing to be valid. The written form requirement may only be repealed by a written agreement between both parties.

Date: 2020.06.09
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