General Order and Payment Conditions

1. General

1.1 DNV 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, having stipulated a Certification Agreement with DNV MEDCERT, also acknowledges that the following documents shall apply in their latest and up to date form at any time, as available on DNV MEDCERT's website;

(i) the "Procedure for the Certification and Conformity Assessment of Medical Devices and Quality Management Systems",

(ii) DNV MEDCERT's "General Order and Payment Conditions"

(iii) the "Price List".

1.3 These General Terms and Conditions shall be applicable exclusively to companies pursuant to § 14 para. 1 of the German Civil Code (Bürgerliches Gesetzbuch, BGB) and legal entities under public law and special funds under public law within the meaning of § 310 para. 1 BGB and shall not apply towards consumers pursuant to § 13 BGB. A consumer within this meaning is a natural person who enters into a legal transaction for purposes that can predominantly be attributed neither to his commercial nor to his independent professional activity. These General Terms and Conditions shall be incorporated in the Agreement as set out in section 1.2 and shall override and exclude any terms and conditions sought to be imposed by the Customer. Terms and conditions of the Customer that are contrary to or deviate from these General Terms and Conditions shall not be deemed accepted unless DNV MEDCERT expressly consents to their validity in writing.

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

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In case DNV MEDCERT's accreditation, recognition or designation has been suspended, restricted, or fully or partially withdrawn, DNV MEDCERT will inform the Customer at least within 10 days.

2. Quotations

2.1 Quotations always relate to the information available at the time of preparation. Cost estimates shall therefore be regarded as preliminary price indications. The Customer acknowledges that changes in the information provided may lead to the need for a renewed certification application and shall apply due care when providing DNV MEDCERT with all requested details at the time of application. The Questionnaire for Certification and the Application for Certification form an integral part of the Certification Agreement.

2.2 Any additional work required due to changes in the assumptions or information on which the quotation was based, as well as any additional work requested by the Customer at any time, will be charged in accordance with the Price List in its applicable version at the time of work execution.

2.3 Customer may cancel or reschedule execution of agreed visits, upon prior written notice to DNV MEDCERT (Notice of Postponement). However, as compensation for the postponement or cancellation, DNV MEDCERT shall be entitled to a cancellation fee as follows:

(i) if the Notice of Postponement is received less than 30 (thirty) days but more than 14 (fourteen) days prior to the agreed date of visit, to 50% (fifty-percent) of the agreed fee;

(ii) if the Notice of Postponement is received within 14 (fourteen) days but more than 7 (seven) days prior to the agreed date of visit, to 75% (seventy-five-percent) of the agreed fee, and

(iii) if the Notice of Postponement is received 7 (seven) days or less prior to the agreed date of visit, to 100% (one-hundred-percent) of the agreed fee.

3. Order Execution

3.1 Orders accepted by DNV 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 DNV 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 DNV 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 DNV MEDCERT that the submitted documents refer to the existing product and/or quality management system. Otherwise, DNV MEDCERT shall be entitled to withdraw from the contract.

3.4 DNV 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 DNV 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 DNV 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 DNV 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 DNV 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 DNV 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 DNV 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 DNV MEDCERT's own purposes. In order to fulfil the requirements set forth in the Annex to Section 9 of the Federal Data Protection Act, DNV 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 DNV MEDCERT, its employees and any external auditors/experts under contract with DNV 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 DNV MEDCERT shall be entitled to have its services partly rendered by subcontractors carefully selected and regarded as qualified by DNV MEDCERT following prior approval by the Customer, which shall not be unreasonably delayed or withheld.

3.13 DNV 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 DNV 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, DNV 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 DNV 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, DNV 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 DNV 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 DNV 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 and 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 DNV 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 DNV 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 DNV 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 DNV 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 DNV 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 DNV 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 DNV MEDCERT.

6.6 Prior to taking any decision in cases described under sections 6.4 and 6.5, DNV MEDCERT shall provide the Customer with an opportunity to present the Customer's view in a hearing, unless there is an urgent reason for DNV MEDCERT to take an immediate decision precluding such a hearing. DNV MEDCERT shall inform the Customer of the decision and specify any required measures. DNV 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 DNV MEDCERT and must demonstrate the implementation of the measures to DNV MEDCERT.

7. Warranty

7.1 DNV 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 DNV MEDCERT's services by the Customer unless the defect has been concealed fraudulently or intentionally caused by DNV MEDCERT.

7.3 The statutory regulations apply in all other respects.

8. Intellectual Property

8.1 For the purpose of this Agreement, each Party shall remain the sole owner of any of its intellectual property and rights thereto existing prior to the date of this Agreement, including, but not limited to, the certification/Notified Body protocols and templates for certificates, reports and checklists. DNV MEDCERT shall be entitled to use, for the purpose of its own certification activities, the know-how acquired in the course of the performance of the Work.

8.2 DNV MEDCERT shall hold all intellectual property rights to the reports and certificates issued to Customer under this Agreement (the Deliverables), including the copyright. Customer shall hold a restricted, non-transferrable, global and royalty free license to use the valid Certificate in accordance with the applicable requirements, and a global, royalty free license to use the reports for its own internal purposes. The reports shall not be disclosed to third parties without the certification/Notified Body's prior written consent.

8.3 The Customer shall only make available the Deliverables or parts thereof to third parties without altering the content, context or original language of the Deliverables.

9. Confidentiality

9.1 Each Party agrees to keep confidential any information it receives from the other Party in course of the Agreement which by denotation or reasonable circumstances is considered confidential to the disclosing Party. The recipient Party shall treat such received information with reasonable care and diligence, not disseminating or disclosing it to third parties without the disclosing Party's prior written consent, provided however that the Certification/Notified Body may share such information with its officers, employees, subsidiaries, affiliates or subcontractors who are subject to confidentiality obligations reflecting the principles herein.

9.2 The obligations hereinabove shall not apply to the extent the information is required to be disclosed by any relevant accreditation Body or certification scheme owner, any competent court, governmental agency, or other relevant public authority in accordance with applicable law, court order or other public regulation. In addition, each Party shall be free to disclose, any information to the extent it: (i) was known to the recipient prior to the information being disclosed by the other Party, or becomes known to the recipient through a third party without any confidentiality obligation; (ii) is or becomes generally available in the public domain through no act or failure to act on the part of the recipient.

9.3 Notwithstanding the above, DNV MEDCERT shall have the right to (i) use for statistical and analytical purposes any information received or generated in the course of the Work, provided that such is kept internal or published only in aggregated anonymous forms; (ii) make reference to the Customer in the certification/Notified Body's marketing; (iii) extend the audit team with third parties insofar required under the applicable scheme or otherwise as set out in this Agreement; and (iv) disclose confidential information to entities in its group of companies that are involved in the provision or follow up of Work.

9.4. The obligations in this section shall survive the completion of the Work or termination of this Agreement and remain in effect for as long as the relevant information can reasonably be deemed to be confidential.

10. Health, Safety and Environment (HSE)

Whenever DNV MEDCERT's performance of the Works involves visits or work on Customer's controlled facility or site, the Customer is responsible for the adequacy, stability, safety and legal compliance of the working environment, including reasonable measures to mitigate or control relevant risks. DNV MEDCERT personnel, including its subcontractors, may refuse to carry out any activity, or visit any area or site, if they in their sole discretion consider that relevant risks are unacceptable or not adequately addressed, contained or otherwise mitigated. Any such decision shall suspend both parties' obligations, excluding Customer's obligation to pay for performed Work,

without any liability or penalty until the parties have agreed on how to proceed.

11. Liability

11.1 The Customer is liable pursuant to statutory law.

11.2 DNV MEDCERT is fully liable for loss or damage due to intent and gross negligence. If DNV MEDCERT breaches a contractual obligation in a slightly negligent manner and if such obligation is essential for the purpose of the transaction on the fulfilment of which the Customer relies (cardinal duty), DNV MEDCERT is only liable for the foreseeable damage that typically occurs for this type of contract. With respect to any other damage resulting from slight negligence, a liability of DNV MEDCERT shall be excluded.

11.3 Unless explicitly agreed upon otherwise in writing, DNV MEDCERT's maximum cumulative liability under or in connection with this Agreement shall be limited to the lesser of (i) a sum equal to five times the annual remuneration paid under this agreement, or (ii) 100 000 USD (one hundred thousand US dollars) except in case of wilful misconduct or gross negligence.

11.4 The foregoing liability limitations and/or exclusions shall not apply to claims resulting from fraudulent concealment of a defect, acceptance of a guarantee and claims pursuant to the German Product Liability Act and to damage arising from injuries to life, body or health.

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

12. Force Majeure

12.1 Neither Party shall be in breach of this Agreement, nor liable for any failure or delay in performance hereunder if the cause of such failure or delay is attributable to events beyond reasonable control of the affected Party (force majeure).

12.2 In the event of a force majeure occurrence, the affected Party shall notify the other Party without undue delay of the particulars of the situation. Either Party shall be entitled to terminate the Agreement with immediate effect should the force majeure endure for more than 30 days.

12.3 DNV MEDCERT may terminate this Agreement, subject where possible to 30 days written notice to Customer, without any liabilities or penalties, if DNV MEDCERT , its ultimate parent company or the ultimate parent company's subsidiaries or affiliates are subject to sanctions or penalties by a government, United Nations, European Union or similar organizations related to the Work which is provided hereunder or would be considered to be illegal or in conflict with applicable law for the certification/Notified Body, its subcontractor and/or its subcontractor's parent companies.

13. Remuneration

13.1 Unless explicitly agreed upon otherwise in writing DNV MEDCERT's "Price List" in its latest up to date version shall apply.

13.2 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. DNV MEDCERT is also entitled to invoice for these additional expenses if a fixed price has been agreed.

13.3 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.

14. Terms of Payment

14.1 DNV MEDCERT is entitled to request advance payments and/or to issue interim invoices covering partial delivery if in its own discretion deems this appropriate for the order.

14.2 The fee shall be due for payment within the due date stated on the invoice. Unless otherwise agreed, the payment term shall be 30 days from the date of the invoice.

14.3 In case of late payments, DNV MEDCERT is entitled to charge a late payment interest according to the applicable law and to claim its other statutory rights.

14.4 No disputes arising between DNV MEDCERT and the Customer shall interfere with prompt payment of invoices by the Customer. The Customer shall have no right to set-off any sums including sums in respect of counterclaims unless such counterclaim is undisputed or has been finally adjudicated upon by a court in accordance with section 16.

15. Place of Fulfilment, Place of Jurisdiction, Applicable Law

15.1 This Agreement shall be governed by and construed exclusively in accordance with the laws of the Federal Republic of Germany under exclusion of the UN Convention on Contracts for the International Sale of Goods (CISG).

15.2 Each party to this Agreement irrevocably agrees that the courts of Hamburg, Germany, shall have exclusive jurisdiction to hear, settle and/or determine any dispute, controversy or claim arising out of or in connection with this Agreement, including any question regarding its existence, validity, formation or termination.

16. Severability and written form requirement

16.1 The full or partial invalidity of individual provisions of this agreement between the Customer and DNV 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.

16.2 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: 2022.10.17

Managing Director: Klaus-Dieter Ziel

DNV MEDCERT GmbH, Hamburg, Germany

HRB 55912