



## Certification Agreement

### DNV MEDCERT GmbH

Pilatuspool 2  
20355 Hamburg

“DNV MEDCERT”

and

### Dr. Arabin GmbH & Co. KG

Alfred-Herrhausen-Str. 44  
58455 Witten  
Deutschland

“Customer”

together “Parties”

conclude the following agreement:

### § 1 Conformity Assessment Procedure<sup>1</sup> and Certification

DNV MEDCERT audits and certifies medical devices and quality management systems in accordance with recognized standards, regulatory and statutory provisions and their guidelines. It performs assessments according to customer's application. If customer's medical devices and/or the quality management system conform to the requirements, customer gets the corresponding DNV MEDCERT certificates in line with acceptable certification and inspection results.

### § 2 Duties of DNV MEDCERT

- (1) DNV MEDCERT is always doing everything necessary to uphold and retain its status as a certification and notified body. Where DNV MEDCERT decides to cease its activities, DNV MEDCERT will inform customer as soon as possible and in case of a planned cessation one year before ceasing the activities.
- (2) In case DNV MEDCERT's designation, recognition or accreditation has been suspended, restricted, or fully or partially withdrawn, DNV MEDCERT will inform customer concerned at least within 10 days.
- (3) As set out in section 9 of the General Order and Payment Conditions, DNV MEDCERT shall respect the confidentiality of 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 Duties of Customer

- (1) Customer is obliged to ensure that the medical devices and/or quality management systems invariably and always conform to the current certificates/certifications.
- (2) 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. Customer hereby also acknowledges that DNV MEDCERT shall surrender documents requested by employees or agents of the recognizing and designating authorities and accreditation bodies as part of their activities. The recognizing and designating authorities are allowed to share all documents and records related to medical device audits with other recognizing and designating authorities that have formal established confidentiality agreements between governments.
- (3) Customer informs DNV MEDCERT of any serious incident, of any field safety corrective action and of any field safety corrective action undertaken in a third country in relation to a device which is legally made available on the Union market and co-operate with DNV MEDCERT and the competent authorities during the investigations.

<sup>1</sup> **Conformity Assessment Procedure** means the activities of DNV MEDCERT as Notified Body in the scope of conformity assessment procedures according to Annexes IX(I), IX(II) and XI(A) of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

(4) Customer shall have in place product liability, professional indemnity and general liability insurances, or similar, with a coverage which reflects the nature and extent of its activities and any applicable regulatory requirements. The insurance shall provide adequate cover for product recall costs and liabilities. Customer shall upon request provide evidence of such cover.

#### § 4 Fees and Charges

Customer is obliged to reimburse DNV MEDCERT any fees and costs occurred in connection with the inspection and certification and this certification agreement. DNV MEDCERT's price list (Document No 520107) in its latest up to date version is an integral part of this agreement and is hereby acknowledged by customer.

#### § 5 Term of Agreement

(1) This Agreement shall remain in full force and effect for a period of 3 (three) years unless terminated by any one of the Parties as set out in this Agreement. The agreement shall automatically be extended by another period of 3 (three) years unless duly terminated as set out below.

(2) Each Party may terminate this Agreement by written notice to the other Party under the following circumstances:

- (a) if the other Party commits a material breach of this Agreement and fails to rectify such within 10 (ten) Working days after receipt of the other Party's written notice;
- (b) with immediate effect if the other Party becomes insolvent, unable to pay its debts as they fall due, or subject to bankruptcy proceedings, receivership, dissolution, liquidation, wind-up or otherwise discontinue business;
- (c) for convenience after serving the other Party a written notice 60 days prior to termination.

(3) If the Customer terminates this Agreement pursuant to § 5 (2) (c) or DNV MEDCERT terminates pursuant to § 5 (2) (a) or § 5 (2) (b), DNV MEDCERT shall be entitled to full remuneration for the Work carried out prior to the termination and for all documented incurred unrecoverable costs as well as any standardized administrative termination fee as per this Agreement.

#### § 6 Use of Certificates and Labels of Conformity

(1) Customer shall be entitled to issue statements related to the certification only in as far as the activities are actually covered by the certificates. The certification must not be used in any way detrimental to the reputation of DNV MEDCERT or in a form that may be considered misleading. Customer is fully responsible for the authorized use and the admissibility of all statements regarding the certificates issued. Upon cancellation, suspension, restriction or withdrawal of the certificates, customer shall be obliged to abstain from referring to the certification in any promotional or advertising materials, and return all certification documents/certificates as requested by DNV MEDCERT.

(2) The certification may only be used as a means of demonstrating that the quality management system/products conform(s) to the legal and standard requirements. The use of the quality management certification system must not convey or promote the impression that a product or service is actually certified in accordance with the corresponding standard.

(3) Customer must ensure that no misleading use is made of any certification document, certification label or certification report or parts thereof. These requirements must also be met in any reference to the certification made by customer in advertising and promotional brochures and material, etc. Customer shall abide by the rules and instructions for use of certification marks in their latest up to date version as shown on our website.

#### § 7 Miscellaneous

(1) The "General Order and Payment Conditions" (Document No 720403) in its latest up to date version is an integral part of this agreement; customer hereby confirms receipt of the relevant contractual document. This especially concerns the items on confidentiality, warranty, liability and place of jurisdiction.

(2) Any provision(s) of this agreement not being effective shall not invalidate the content of the remaining provisions. Both parties shall be obliged to replace any incorrect provisions with valid provisions that have essentially the same economic effect.



**§ 8 Special Conditions**

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.

Hamburg, 2023-04-04

This Agreement replaces the agreement dated 2022-09-23

Date of first issue: 2022-09-23

for **DNV MEDCERT GmbH**



Klaus-Dieter Ziel  
Managing Director

for **Customer**



signature

BIRGIT ARBIN

name in printed letters

CEO / QMB / PRRC

position

The following documents apply in their latest up to date version as shown on the DNV MEDCERT website:

- General Order and Payment Conditions (Document No 720403)
- Price list (Document No 520107)
- Procedure for the Certification and Conformity Assessment of MD and QMS (Document No 7201)
- Rules and instructions for use of certification marks

Document signed  
by: Klaus-Dieter Ziel, DNV MEDCERT GmbH  
on: 04.04.2023 16:26