TÜVNORD

TÜV NORD CERT GmbH

Specific certification conditions MDR

CONTENT

This document has been approved according to CERT-401-VA-007. Details are available from the QM-Department.

1. SCOPE AND DEFINITION

1.1. These Specific certification conditions MDR describe the rights and duties of the Applicant and of TÜV NORD CERT GmbH as the Notified Body as well as further conditions for the performance of conformity assessment procedures under the European medical devices regulations as amended from time to time.

1.2. Conformity assessment procedures are understood to include activities such as performing assessment of conformity with the requirements of regulations, directives or technical standards using test methods or calculations, expert opinions, tests to prove specific product characteristics as well as inspections of quality assurance systems by means of audits.

1.3. The basis for assessment are the mandatorily applicable EU regulations or MDCG guidance documents or harmonised standards as well as common specifications or, if applicable, other technical standards or the relevant directives of the European Union in their currently valid versions and the national regulations underlying the designation.

2. PRIOR TO SUBMISSION OF A CONFORMITY ASSESSMENT APPLICATION

2.1. Prior to the submission of an application for a conformity assessment procedure, the Applicant shall provide the Notified Body with essential information about its company, its operating facilities covered by the conformity assessment procedure, its suppliers and subcontractors, who may have a significant influence on the safety and performance of the devices, and the devices to be covered by the conformity assessment procedure, in order to enable the Notified Body to gain an overview of the scope of the service to be offered or identify potential problems in providing such service.

This information will also serve as a basis for subsequent tender preparation.

3. APPLICATION FOR CONFORMITY ASSESSMENT PROCEDURE

3.1. The Applicant shall submit an application to the Notified Body for conformity assessment, extension of the scope or renewal of a conformity assessment.

3.2. The Applicant shall represent in its application that no parallel application has been filed with any other notified body regarding the same quality management system for this device, or it shall submit information on previous applications, if any, regarding the same quality management system for this device together with its application (MDR Annex IX, 2.1).

3.3. If the manufacturer's application is filed by its authorised representative within the meaning of MDR Art. 2 (32), the authorised representative shall also submit the mandate issued by the manufacturer for the designation of an authorised representative and the declaration of intent of the authorised representative to accept this mandate. (MDR Annex IX, 2.2 b). The application shall include both the name of the manufacturer, its legal form, and the full address as well as the name of the authorised representative and the address of the registered place of business of the authorised representative.

3.4. Together with the application, the Applicant shall send the necessary documentation and further information as may be required for the order to the Notified Body.

3.5. The prerequisite for processing orders for conformity assessment is the availability of all necessary documents and information and access to the manufacturing sites to be assessed in the audit, unless other arrangements have been made with the Applicant. If the necessary documents and information and the access to the manufacturing sites to be assessed in the audit are not provided by the agreed time, delays in the planned process may be unavoidable for which TÜV NORD CERT GmbH cannot be held responsible. To avoid such delays, the Applicant shall be obliged to regularly provide the Notified Body with information on non-production times for all locations and manufacturing sites concerned and for any subcontractors covered by the audit.

3.6. In case of any discrepancies regarding the product’s qualification as a medical device or the classification between the client and the notified body, it is the applicant’s responsibility to refer this to the competent authority of the Member State in which the manufacturer or the authorized representative has it’s registered places of business, for clarification and decision. The assessment process for that project will be rejected and requires a re-application after receiving the authorities’ decision.

4. EARLY TERMINATION OF THE CONFORMITY ASSESSMENT

4.1. If the Applicant decides at any time after submission of the application to discontinue the order, the Notified Body shall be obliged to make this information available to the other notified bodies via the European database system. In case of early termination

of the conformity assessment procedure by the Applicant before completion of the assessment or certification, the Notified Body shall invoice the service provided by that time as well as any further costs resulting from such early termination of the contract.

5. CONFORMITY ASSESSMENT PROCEDURE

5.1. The conformity assessment activities (assessment, decision on certification, surveillance, etc.) result from the requirements of, among others, the Regulation (EC) No. 2017/745 as well as the MDCG GUIDANCE or harmonised European standards (according to MDR Art. 8(1) and (2)) or common specifications (according to MDR Art. 9), full compliance with them being a prerequisite for the issuance of an EU certificate.

6. SURVEILLANCE PHASE

6.1. The Applicant undertakes to maintain the approved quality management system such that its suitability and effectiveness remain ensured.

6.2. The Notified Body shall specify how and when the relevant surveillance activities will be carried out. In addition to the surveillance audits performed at least once a year, these surveillance activities shall also include unannounced audits or audits related to specific events and audits of subcontractors and suppliers as may be required. Moreover, surveillance activities shall also include surveillance of compliance with all conditions imposed on applicants and related to certification decisions, such as updating clinical data at specified intervals.

6.3. The applicant assures to establish and keep up to date a systematic procedure for the determination of information from the post-production phase. Complaints are systematically evaluated by the applicant in order to carry out necessary corrections. The applicant grants TÜV NORD CERT access to these records or submits them on request.

6.4. Stocks of finished devices bearing a CE marking with the identification number 0044 shall be made known to the Notified Body immediately on request together with an affidavit suitable for use before a court of law.

6.5. During the validity period of the EU certificates, the Applicant shall be obliged to inform the Notified Body immediately in writing of any incident (MDR Art. 2(64)), any safety corrective action (MDR Art. 87) and any withdrawal (MDR Art. 2(63)) and keep it informed of their further course. To this end, the Applicant shall send all decisions of the competent authorities and the notification of the completion of measures to the Notified Body in addition to the corrective actions (MDR Art. 2(67)) and the notification to the authorities.

6.6. During the validity period of the EU certificates the applicant shall be obliged to inform the notified body of any court judgement / ruling / decision pertaining to the products or quality system covered by the certificate without undue delay.

7. CHANGES DURING THE VALIDITY PERIOD OF THE CERTIFICATE

7.1. During the validity period of the EU certificates, the Applicant shall inform the Notified Body of any planned substantial changes to the quality management system or the product range covered by it (Annex VII 4.9).

The Notified Body shall evaluate the proposed changes and decide on any necessary action to determine whether conformity with the requirements is maintained with these changes.

The Applicant shall be obliged to implement the planned changes only upon full assessment and approval by the Notified Body.

7.2. Moreover, the Applicant shall be obliged to notify the Notified Body without delay of any changes according to Annex IX, 4.10 (such as changes to the approved design, the intended use of the device or information on the device, substances contained in a device or used for the manufacture of a device and covered by one of the special procedures according to Annex VII, 4.5.6).

7.3. Furthermore, the Applicant shall be obliged to provide the Notified Body with all plans and relevant information required for the assessment and approval, if applicable, of the change (MDR Annex IX 4.10).

7.4. The Applicant shall provide the Notified Body, without being requested to do so, with the periodic safety update report (PSUR according to MDR Art. 86) at the required intervals as per Article 86,1. For class III or implantable devices, the applicant shall submit the PSUR by means of the Eudamed Module Vigilance and as a part of the Technical documentation.

7.5. In addition, the Applicant shall submit for all implantable and class III devices without being requested to do so, to the Notified Body the draft of the summary of safety and clinical performance (SSCP according to MDR Art. 32). The SSCP shall be prepared following the structure and content as given in the implementing acts or MDCG Guidance. The report shall be

validated by the Notified Body and then uploaded to the Eudamed database.

8. UNANNOUNCED AUDITS AND DEVICE CHECKS

8.1. During the conformity assessment procedure, the Notified Body shall perform at least one unannounced audit of the Applicant and, if applicable, of the suppliers/subcontractors within the certification cycle of five years; this frequency may be increased depending on the risk of the devices or in case that there are indications of defective devices or for similar reasons. Unannounced audits shall be performed on at least one day by at least two auditors at the expense of the Applicant, the duration depending on the number of devices or groups of devices and the conformity assessment procedure selected.

8.2. The Applicant shall fully cooperate with the audit team to ensure smooth conduct of the unannounced audits. The Applicant shall provide the audit team with full access to the relevant premises, records and personnel. It shall promptly provide the documentation and information necessary for the smooth conduct of the unannounced audit.

8.3. The Applicant shall ensure unrestricted access of the audit team also to the premises of suppliers or subcontractors to the extent this is necessary for verifying compliance with the technical documentation and regulatory requirements. It undertakes to ensure that the suppliers/subcontractors will fully cooperate with the audit team for the unannounced audit.

8.4. If it necessary for conducting the unannounced audit that visas are applied for and issued or other measures are taken (e.g. to ensure the safety of the audit team), the Applicant shall take all necessary steps to ensure that such visas or other measures are issued or implemented.

8.5. During the unannounced audits, the Notified Body may draw samples preferably from the current production in order to check, or have checked, the conformity of the device with the technical documentation and the applicable regulatory requirements.

As part of the conformity assessment of the sample devices, the Notified Body shall check the traceability of all critical components and materials as well as the traceability system of the manufacturer.

8.6. The Applicant shall make available to the audit team the required technical documentation and all previously recorded test results.

8.7. The inspection of the sample devices shall include the assessment of the documentation and, if necessary, a device test. Such test shall be performed according to the specifications laid down by the manufacturer in the technical documentation or test instructions and may be performed by the Applicant or the supplier of the component under the supervision of the Notified Body to the extent required by the Notified Body.

8.8. Also during the unannounced audits, the Notified Body may audit in detail at least two critical processes, such as the development process, the preparation of device specifications, the procurement and testing of procured materials and services, the manufacture of components, the manufacturing process, the sterilisation process, the batch release, the packaging or quality control.

8.9. Instead of, or in addition to, the unannounced audits on the premises of the Applicant or its suppliers/subcontractors and under the condition that the costs are fully borne by the Applicant, the Notified Body may take samples of the devices from the market, if appropriate with the assistance of the competent authorities, to perform, or have performed, inspections and tests. In preparation for these inspections and tests, the Applicant shall make available the necessary technical documentation and the records having led to the approval of the devices as well as the previous test results.

8.10. The certificate may be restricted or even revoked if the unannounced audit or the sample checks cannot be, or cannot fully were, performed or if the results are not appropriate.

9. PERFORMANCE OF AUDIT

9.1. By the time the certification audit takes place and prior to the surveillance audits, the Applicant shall be obliged to perform a complete internal audit (all elements of the relevant standard as well as the locations / production sites relevant for the scope of the EU certificate or certification and, if necessary, development sites need to be audited) as well as an assessment of the quality management system.

9.2. The Applicant shall designate a contact person from the company management to be responsible for the execution of the audit.

9.3. To the extent the scope provides for a Stage 1 Audit, the Applicant undertakes to make available to the audit team or to the Notified Body at the agreed time all valid documents relating to the management system (manual, process instructions, process descriptions,

other relevant documents, records of internal audits and management reviews performed) monolingual throughout, either in German or English language.

If parts of the original documentation have been prepared in another language, it shall submit a translation into the German or English language together with the original.

For all procedures, the relevant documents shall be made available in good time (14 days) before the audit.

9.4. Any identified non-conformities shall be presented to the Applicant during the final meeting.

9.5. Non-conformities, if any, identified in the Level 1 Audit shall be remedied by the time the Level 2 Audit is performed.

If the non-conformities from the Level 1 Audit have not been remedied before the Level 2 Audit, the Notified Body may decide not to perform the Level 2 Audit on the scheduled date, but only after such non-conformities have been remedied on a date agreed in advance with the Applicant.

9.6. The services of the Body shall relate solely to the functionality and correctness of the audited quality management system but not to the functionality, correctness or freedom from defects of the individual medical device manufactured by the Applicant.

9.7. The audit team shall be entitled to terminate the audit prematurely if successful completion of the audit cannot be expected.

10. ASSESSMENT OF TECHNICAL DOCUMENTATION

10.1. The Notified Body shall perform assessments of the technical documentation with the same level of scrutiny for all classes of devices as part of the conformity assessment procedures.

10.2. The Applicant shall inform the Notified Body of all devices to be added to the scope of the EU certificate and provide the Notified Body upon request with the most recent, searchable, organised and easily readable version.

10.3. The Applicant shall keep available the required technical documentation as well as the technical documentation on post-market surveillance monolingual throughout, either in German or English language according to the requirements of Article 10.4. If parts of the original documentation have been drawn up in another language, it shall submit a translation into the German or English language together with the original.

On request, the Applicant shall make available to the Notified Body the current, searchable, organised and easily readable version of the technical documentation. In doing so, the specifications of the Notified Body shall be considered with regard to the assignment of the individual documents to the requirements in order to ensure smooth conduct of the assessment, and the technical aids provided for transmission to the Notified Body shall be used.

10.4. On request of the Notified Body, the Applicant shall make available free device samples together with the technical documentation. The Applicant undertakes to comply with the required export control specifications.

10.5. The Applicant shall not be entitled to any compensation for damage to the device sample as may have occurred during the performed tests.

Upon completion of the inspection and tests, the device samples shall be returned to the manufacturer or, at the discretion of TÜV NORD CERT, disposed of, for a charge if necessary.

11. RENEWED APPLICATION

11.1. To ensure smooth transition at the end of the certification cycle, the Applicant shall submit a new application to the Notified Body for performing a conformity assessment procedure in due course (typically 6 months) before the end of the validity of an EU certificate.

11.2. Together with the renewed application, the Applicant shall forward with the order to the Notified Body the necessary documentation and any further information required for the order.

11.3. The Notified Body shall examine any documents and information submitted before it performs a further conformity assessment procedure.

12. CERTIFICATION DECISION

12.1. An objection may be raised to certification decisions and a complaint may be lodged against the conduct of procedures (see point 19).

13. EU CERTIFICATES AND CERTIFICATIONS

13.1. Upon issuance of the EU certificate by the Notified Body, the Applicant obtains the right to affix to the devices the CE marking together with the identification number 0044.

13.2. The permission for using the CE marking with the identification number 0044 shall only be valid for that particular company and for those particular operating facilities as well as for those particular devices which are covered by the scope of the EU certificate. In case of an intended relocation of an operating facility or transfer of the company to another company or to another company owner, the Applicant shall inform the Notified Body in good time. Only the Notified Body shall be entitled to transfer the EU certificate to any third party. The Notified Body shall decide on the further procedure.

13.3. The EU certificate shall only be valid for the complete device. However, in special cases the Notified Body may allow the Applicant to disassemble the CE-marked devices for shipping purposes to the extent normal for installing the device into a plant. Moreover, permission may be given to dismantle the product further into its individual parts, if the Applicant designates an assembly shop, which must then be subjected to the control by the certification body in the same way as the initial manufacturing site.

13.4. The Notified Body reserves the right to publish for consumer information a list of certified clients, applicable normative documents, the scope and the geographical location. If requested, access to certain information can be restricted.

13.5. The invalidation or lapse of a certificate may be published.

13.6. The Applicant is responsible for ensuring that the conformity mark used corresponds to the scope of the certificate.

14. RESTRICTIONS / SUSPENSION / REVOCATION / TERMINATION OF THE RIGHTS OF USE

14.1. An EU certificate shall lapse with immediate effect and without prior notification if inter alia

- the general contract for certification ends,
- the Applicant renounces the EU certificate,
- the Applicant has not accepted changes to the terms and conditions of business, the terms and conditions of certification or the prices of TN CERT as binding for it after a specified period has expired,
- the Applicant goes bankrupt or an application against it for the opening of bankruptcy proceedings is rejected due to lack of assets,
- surveillance audits cannot be performed for reasons attributable to the Applicant,
- the rules underlying the EU certificate have been changed and, if applicable, transitional periods have expired. The validity of the EU certificate shall be extended if it is proven by a follow-up check at the Applicant's expense within a specified period that the certified devices or the certified quality management system also complies with the new regulations.

14.2. An EU certificate may also be suspended, invalidated or cancelled by the Notified Body if

- the certified management system persistently or seriously fails to meet the certification requirements, including the effectiveness of the management system.
- the fees have not been paid within the specified period following a reminder. If the fees do not relate to a specific EU certificate, the Notified Body shall assign the measure to a particular certificate,
- the Applicant continues to use an improper CE marking with the identification number 0044 on its devices although the Notified body has advised it of the unlawful use of the CE marking with the identification number 0044 and urged it to use the marking properly,
- the Applicant continues to violate its statutory reporting obligations towards authorities after a warning from TÜV NORD CERT.

14.3. A certificate may also be declared invalid or terminated by the Notified Body if

- devices bearing the CE marking and the identification number 0044 fail to comply with the certified scope of the EU certificate,
- defects not evident or not detected during the test are subsequently found in the devices,
- the product or the product category was incorrectly designated as medical devices,
- the medical device or the medical device category was assigned to a class which is too low, and hence a false declaration has been made for it,
- the inspection of the devices bearing the CE marking and the identification number 0044 reveals defects,
- the CE marking with the identification number 0044 is used for misleading or otherwise inadmissible advertising,

- due to facts which could not be identified at the time of testing, the continued use of the CE marking with the identification number 0044 is not justifiable in view of its meaningfulness in the market,
- proper performance of the audits in the operating facilities of the Applicant or in any other operating facility is not proven within 4 weeks despite a relevant written request by the Notified Body,
- the Applicant refuses to allow the audit team of the Notified Body to inspect the operating facility or to remove devices for the Notified Body's inspection.

14.4. The Notified Body may also suspend an EU certificate for a limited period of time if circumstances exist which would justify the withdrawal, revocation or restriction of the certificate according to the above provisions, but such circumstances will foreseeably be of limited duration only. The right to withdraw, revoke or restrict the EU certificate shall not be limited by the right to suspend.

14.5. The Notified Body shall be entitled to suspend or terminate an EU certificate and thus the entitlement to use the CE marking with the identification number 0044 if the certification body subsequently becomes aware of relevant new information regarding the assessment of the certification procedure or the outcome of the certification procedure.

14.6. Before any decision is made on the restriction, suspension, withdrawal or revocation of the EU certificate, the Applicant or its authorised representative based within the European Economic Area shall be given the opportunity by the Notified Body to present its views, unless such hearing is not possible due to the urgency of the measures to be taken. The Notified Body shall provide the Applicant with a written substantiation of any such withdrawal or revocation of the EU certificate.

14.7. Following the restriction, suspension, withdrawal or revocation, the Applicant shall be prohibited from continuing to use the certificate issued by TÜV NORD CERT and the CE marking with the identification number 0044.

14.8. Upon expiry or invalidation of an EU certificate, the certificate shall be returned to the Notified Body, even if a permission exists to distribute the remaining stocks bearing the CE marking and the identification number 0044.

14.9. Upon expiry of the validity of an EU certificate, the use of the CE marking with the identification number 0044 may be permitted for devices of the existing stock of ready-to-use products, however only for a maximum period of 12 months. Permission may be given to assemble the prefabricated parts already existing at the time the validity of the EU certificate expires and intended for the manufacture of the finished device to be specified by the Applicant, but only for a maximum period of 6 months from the date on which the validity of the EU certificate expires.

15. INFRINGEMENTS OF THE CERTIFICATION CONDITIONS

15.1. The Notified Body shall be entitled to demand a contractual penalty of up to EUR 10,000.00 for each case of culpable infringement of these terms and conditions of certification, in particular in case of unlawful use of a CE marking with the identification number 0044. Unlawful use of a CE marking with the identification number 0044 shall also include any case of offering or placing on the market devices bearing a CE marking with the identification number 0044 before a certificate has been granted or any case of non-permissible advertising.

15.2. The parties agree that, in the internal relationship between the parties, the Applicant shall be solely responsible for the lawful use and utilisation of the CE marking with the identification number 0044, in particular also with regard to competition law.

16. OCCUPATIONAL SAFETY REGULATIONS

16.1. Applicant

- Prior to the performance of the order, the Applicant shall provide information on hazards and exposures, which may emanate from the working environment in the company of the Applicant, including information on hazardous substances in test specimens. The Applicant shall provide information on whether and, if so, to what extent health examinations are required for the commissioned activities.
- The Applicant shall provide reasonable first aid, alarm, rescue precautions, and designate contact persons and responsibilities.
- The Applicant shall ensure that a member of staff of the Applicant will always accompany employees of the Notified Body when they perform their activities.
- The Applicant shall instruct the employees of the Notified Body using risk assessment(s) and oper-

ating instruction(s), including on emergency numbers and assembly points in emergency cases as well as on the operation and safety of any equipment to be used.

- The Applicant shall provide, free of charge, any personal protective equipment (helmet, safety shoes, hearing protection, safety goggles) as may be necessary beyond those provided by the Notified Body. The employee of the Notified Body may only perform his/her activities when safe conditions have been established. He/she shall have the right to refuse activities in case of unreasonable hazards/burdens.

16.2. TÜV NORD CERT may postpone, interrupt, terminate or cancel the contractually agreed provision of services if, in TÜV NORD CERT's opinion, there is a risk to the health of its employees, subcontractors or suppliers due to an epidemic threat, such as Covid-19, natural disasters, a terrorist threat, etc. Insofar as TÜV NORD CERT takes advantage of this right, there shall be no liability for damages and no obligation to pay contractual penalties or any other liability on the part of TÜV NORD CERT.

17. PUBLICATION OF TEST REPORTS AND CERTIFICATES

17.1. The holder of EU certificates or reports may disclose them only in their full wording, indicating the date of issue. Any publication or duplication shall be subject to the prior consent of the issuing body.

18. COMPLAINTS

18.1. An objection may be raised to certification decisions and a complaint may be lodged against the conduct of procedures.

18.2. Any complaints/objections received shall be investigated and dealt with appropriately and reasonable efforts shall be made by the Notified Body to resolve the issue.

18.3. If the Notified Body has rendered a defective service, the Applicant shall give it the opportunity for supplementary performance at least twice within a reasonable period, unless this is unreasonable in the individual case or special circumstances exist which, after weighing the interests of both parties, justify the immediate withdrawal by the client. If such supplementary performance fails, the client shall have the right to reduce the remuneration or withdraw from the contract; claims in case of withdrawal and for damages shall not exist if the deviation from the contractually owed quality is only insignificant.

19. DATE OF EFFECTIVENESS AND AMENDMENTS TO THE TERMS AND CONDITIONS OF CERTIFICATION

19.1. The terms and conditions of certification shall take effect as of 2025-09-15.

19.2. After new terms and conditions of certification have been drawn up, the present terms and conditions shall cease to be valid after a transitional period of 6 months.

20. ACCESS OF AUTHORITIES AND TÜV NORD CERT PERSONNEL

20.1. Upon placement of the order, the Applicant agrees to grant access to its premises and assessment records to

- the employees of the designating, accrediting, authorising, recognising authorities and bodies of TÜV NORD CERT responsible for the area within the framework of supervision of the Notified Body,
- the employees, or persons acting on behalf, of TÜV NORD CERT acting as observers or trainee assessment personnel.