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1 Scope

This procedure applies to the conformity assessments of medical devices according to the Medical Device Regulation (EU) 2017/745 (MD) and certifications of quality management systems according to recognized standards, regulations and statutory provisions, including those under the Medical Device Single Audit Program (MDSAP), the Malaysian Medical Device Act 2012, Act 737, the Malaysian Medical Device Regulations, the requirements for participating EU Notified Bodies Partner under the TCP Technical Cooperation Program (Taiwan) and their guidelines DNV MEDCERT offers. This procedure is applicable after a customer signs an application and the certification agreement.

2 Our Quality Policy

We ensure the enforcement, maintenance and continuous improvement of our quality management system through ▸

- Periodical internal and external audits, including assessment of the effectiveness of our quality management system
- Plan and define our company structure and our processes
- Delegation of tasks and responsibilities to internal and external experts
- Maintenance and improvement of staff qualifications through training and continuous education
- Provision and availability of necessary financial stability and resources
- Control of impartiality by the Committee for Safeguarding Impartiality

Our quality policy is published by the Managing Director throughout the company in order to ensure that it is understood and considered by all our staff, including our subsidiaries and subcontractors. We review our quality policy at least annually within the management review. It provides us a framework for establishing and reviewing our quality objectives.

This is our quality policy ▸

- The neutrality and competence of our services are the basis for the trust placed in us by health professionals, patients, authorities, and the medical devices industry.
- We are an integral part and we are fully aware of our role for the implementation of European Directives and Regulations, as well as the country-specific requirements of MDSAP participating Regulatory Authorities, focusing on the safety of patients, users, and third parties.
- The appropriate allocation of a continuous and high-quality service is our responsibility. Top Management undertakes all steps needed and provides the necessary means to achieve this goal. This includes, for example, the employment of a sufficient number of qualified staff members to be able to perform the certification and conformity assessment processes in compliance with the requirements.
- All documents, information, product samples, and any other objects submitted to us by our customers shall be treated as "strictly confidential" in all cases and by all staff members. This covers also the members of our Scientific Advisory Board, our contractors and DNV MEDCERT subsidiaries. All individuals, groups and companies involved in any certification or conformity assessment process are obliged by contract to maintain strict confidentiality.
- We get the requirements of our customers, review them, and meet them within the scope of the regulations and requirements.
- Our service is available to all interested parties anywhere in the world. All customers are treated equally regardless of nationality, organization, company or individual.
- We ensure that our activities are offered without any commercial or financial pressure and exclude any bias in the certification or conformity assessment activities.

- We ensure impartiality, independent decisions and a fair and correct relationship to every customer. This implies the prevention of intimidation and self-interested threats, the keeping of a strict separation between assessment and certification/conformity assessment activities on one hand and independence of personnel from external influence on the other. We maintain our neutrality and the exclude any consulting or similar activity.
- We have installed a Committee for Safeguarding Impartiality which consists of representatives of parties affected by our activities.
- We fully understand the importance of impartiality and ensure the objectivity in all our certification and conformity assessment activities. We will not provide any certification in cases when a relationship poses an unacceptable threat to our impartiality.
- We manage any foreseeable conflict of interest.
- We will never outsource audits to any other organization.
- Consultant companies are not permitted to market or link their activities to our certification activities. We will take action if we see inappropriate claims from consulting companies stating or implying that certification/conformity assessment would be simpler, easier, faster or less expensive if customers are using their services. In addition, we will not state or imply that certification/conformity assessment would be simpler, easier, faster or less expensive if a specific consultancy organization were used.
- We will never certify the quality management system of another certification or notified body, offer or provide internal audits to our certified customers.
- Neither DNV MEDCERT nor any of our subcontractors are allowed to provide consultancy services in the same scope we are accredited or designated.
- To avoid any conflict of interest, we ensure that we will not use any personnel that was involved in a consultancy role with the customer in question at least within three years following the end of such consultancy.
- We will take action and respond to any threats to our impartiality arising from actions of other persons, bodies or organizations.
- All our personnel as well as all our subcontractors are not allowed to offer or provide any services within the scope we are accredited, designated or recognized, which may jeopardize the confidence in our independence, impartiality or objectivity.
- We assure, that the remuneration of our top-level management or that of our assessment personnel or that of subcontractor involved in assessment activities, do not depend on the results of assessments.
- We require all our staff and all our subcontractors to reveal any circumstances known to them that may present them or us with a conflict of interest. In such cases we will not use any staff or subcontractor unless they can demonstrate that there is no conflict of interest.
- We are and must stay independent from the manufacturer, authorized representative distributor or companies sterilizing or placing on the market systems or procedure packs.
- All our personnel as well as all our subcontractors are not allowed to be the designer, manufacturer, supplier, installer, purchaser, seller, marketer, owner or maintainer of the devices we assess, nor the representative of any of those parties.
- We operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interest of small and medium-sized enterprises.
- All our personnel as well as all our subcontractors observe professional secrecy in carrying out their tasks, except to our national authorities or any competent authority for medical devices in the EU or the Commission, or the MDSAP participating Regulatory Authorities.
- All our personnel as well as all our subcontractors protect proprietary rights.
- We remain fully responsible, even if we are using subcontractors for specific tasks.
- We ensure that our advertising or promotional activities in no way imply or are capable of leading to an inference that our certification or conformity assessment activities will offer customers earlier market access or be quicker, easier or less stringent than that of other certification or notified bodies.
- We use the accreditation, designation and recognition marks only for premises that are included in our scope.

- We make claims of our accreditation, designation and recognition only in respect to activities which has been granted accreditation, designation or recognition.
- We will never use our accreditation, designation or recognition in a manner that brings the accreditation body, or designating or recognizing body into disrepute.
- We will never make a statement regarding accreditation, designation or recognition that may be considered misleading or unauthorized.
- We will never allow the fact that our accreditation, designation or recognition is used in a manner that anybody may imply that a product, process or person is approved by the accreditation body or by designating or recognizing authority.

3 DNV MEDCERT Staff and Subcontractors

DNV MEDCERT ensures that certifications and conformity assessments are performed by suitably qualified staff and subcontractors. The names of the staff and subcontractors performing these activities are disclosed to the customer. Depending on need, DNV MEDCERT may appoint subcontractors for specific tasks in an assessment or certification process. The name of the subcontractor (e. g. expert or lead auditor from the Scientific Advisory Board, laboratory or a DNV MEDCERT subsidiary) including an overview of the experience and qualifications are disclosed to the customer in advance. The customer can either agree or disagree in writing to the use of the subcontractor.

Subcontractors involved in an assessment or certification process are not allowed to participate in an advisory or consultancy manner in the same scope we are accredited, recognized or designated, nor as representative for the design, production, sales or maintenance of products or quality management systems concerned. In addition, subcontractors are not allowed to be in any obligatory relationship with the customer.

4 Independence, Objectivity, Impartiality and Confidentiality

DNV MEDCERT and its subsidiaries are neither involved in any consultancy nor act as authorized representative. If subcontractors participate in a certification or conformity assessment process, it is ensured that the subcontractor is not involved in any consultancy in the relevant area. The DNV MEDCERT staff and subcontractors used in the certification and conformity assessment processes must be independent from any economic interest in the product and of the competitor of the customer.

We ensure that the DNV MEDCERT staff and subcontractors participating in a certification or conformity assessment process are neither an adviser, consultant in the same scope we are accredited, recognized or designated, authorized representative or be involved in the design, construction, manufacturing, marketing, installation, servicing, installation, maintenance, supply or the user[1] or owner of products, nor involved in the design, construction, implementation or maintenance of the quality management system being audited. We also ensure that the staff and subcontractors did not advise the customer or be in any other type of binding relationship with the customer, its authorized representative, supplier or any competitor of the customer, which may jeopardize their confidence in their independence, impartiality or objectivity, during the last 3 years.

DNV MEDCERT ensures the impartiality of all assessment and verification staff and ensures that their remuneration do not depend on the number of audits and verifications they carry out, nor on the results of their assessment and verification activities.

Our staff, subsidiaries and subcontractors carry out their certification and conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field. They are free from pressures and inducements, particularly financial, which might influence their judgement or the results of their certification and conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

[1] The term ‘user’ in this context does not mean to exclude the use of experts for the assessment and verification of clinical data

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 or regulated by law. 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.

5 Certification of Quality Management Systems and Conformity Assessment Processes

The customer applies to DNV MEDCERT to perform a certification of the quality management system and/or conformity assessment process and encloses all documents, information and material, as requested and required by DNV MEDCERT. All documents submitted by the customer as well as any correspondence must be either in German or in English. Exception is correspondence with Chinese customers in Chinese as it is addressed directly to the Chinese employees. If required translation by internal staff is guaranteed.

After receipt of the application, DNV MEDCERT checks the feasibility of the application and appoints a Lead Auditor and, if necessary, other members of the audit team and the required experts. The customer has the right to complain and/or appeal, if the application is declined.

If the quality management systems certification and/or conformity assessment processes according to the Medical Device Regulation (EU) 2017/745 requires an assessment of the technical documentation, these documents, information or material, as requested and required by DNV MEDCERT and the Medical Device Regulation (EU) 2017/745, must be available prior to the on-site audit. The technical documentation must proof compliance to the applicable “General Safety and Performance Requirements” of Annex I, the “Technical Documentation“ of Annex II and “Technical Documentation on Post-Market Surveillance” of Annex III of the Medical Device Regulation (EU) 2017/745. If the process requires any testing of medical devices the test items must be available on request by DNV MEDCERT.

The Lead Auditor or other member of the audit team assesses the completeness and compliance of the submitted documentation with the requirements of the quality standard and/or Annex IX or XI of the Medical Device Regulation (EU) 2017/745. The assessment is done according to the applicable DNV MEDCERT procedures. In advance to an on-site audit, the customers receive an audit plan, which outlines the details.

The audit plan includes the following ▸

- The selected Standard(s) / the applicable Annex of the Medical Device Regulation (EU) 2017/745
- Date and schedule of the audit
- Name of auditors/experts
- Planned visits at departments, facilities and locations.

The audit starts with a meeting with the top management and the quality management representative of the customer. The audit team will audit the customer according to the audit plan accompanied by responsible personnel of the customer. They audit team will use check lists and make notes about of their findings.

At the end of the on-site audit, the Lead Auditor provides a preliminary verbal report and a written audit summary to the customer. The customers get a full report after the audit.

During initial audit and annual surveillance audits, technical documentation assessment(s) are assessed according to Annex IX and Annex XI of the Medical Device Regulation (EU) 2017/745. The customer receives a report for each technical documentation assessment.

In case there is any non-conformity in the quality management system or the technical documentation assessed, the customer must propose suitable corrective actions and deadlines for their implementation, including a root caused analysis. Depending on the complexity of these actions, an additional special on-site audit related to the implementation of the corrective actions may be required. The Lead Auditor/Expert assesses the implemented and/or proposed corrective actions for their suitability to close each non-conformity.

6 Decision Regarding Certification

The results of the audits and technical documentation assessment(s), including assessed nonconformities (if there are any) are forwarded to the DNV MEDCERT in-house Certification Body. The Certification Body appoints an assessor, who was not involved in this specific certification/conformity assessment process, to check the documents for compliance with the rules and procedures of DNV MEDCERT´s quality management system. The Certification Body decides whether or not the assessment results lead to the issuing, refusal reduction, extension, suspension or withdrawal of a certificate.

The customer receives a final assessment report from DNV MEDCERT including a statement indicating as to whether or not the certificate can be issued or to what extent additional corrective actions must be performed prior to the issuance of a certificate. The certificate applies exclusively to the holder of the certificate and the products, activities and production facilities mentioned on the certificate. Each certificate shows an expiry date. The issuing of the certificate may be imposed with further conditions and/or obligations and their implementation must be proven by the customer in due time.

The customer may file a complaint and/or appeal against the decision of DNV MEDCERT. Our procedure “Verification of Complaints” describes the process and is available from our website under Download/Medcert Documents/Verification of Complaints.

DNV MEDCERT has the obligation to inform the relevant authorities about certificates being issued, suspended, withdrawn, rejected, reduced and reinstated.

7 Surveillance and Post-Certification Monitoring

DNV MEDCERT regularly monitors whether the requirements for the maintenance of a certificate are fulfilled. In this regard, the surveillance of certificates is done by annual audits, or, in case of product certificates, done by regular queries of the product status and necessary product assessments due to modifications or new requirements of the product.

DNV MEDCERT checks relevant databases and analyses information about certified customers and products. Based on the results of this surveillance, further activities may be necessary to clarify the situation. The decision about these activities is done based on the individual situation and according to the regulatory and normative requirements.

Due to certain reasons, i.e. investigate complaints, results of changes, suspended certificates, or on request of our designating or recognizing authority, additional special audits may be necessary. Special audits incl. planning, conducting etc., are adjusted to the particular situation. We inform the customer in advance and submit the audit plan at the earliest possible time. After the special audit, the customer receives a report and/or the final decision. In case of a technical documentation assessment, an additional review might be necessary.

Upon any violation of the Certification Agreement, the rules specified in that agreement and in the General Order and Payment Conditions apply.

DNV MEDCERT has the right to conduct observed audits, short notice audits, “for-cause” reviews and unannounced audits. Unannounced audits are either planned unannounced audits according to Medical Device Regulation (EU) 2017/745, Annex IX, Section 3.4 or unannounced audits based on an individual situation or on request of our designating or recognizing authority. In case of unannounced audits, the customer gets no information or audit plan in advance. We report the results of the unannounced audit in an audit report and submit it to the customer.

The customer is obliged to monitor continuously the manufacturing of certified products for compliance with the requirements on which the assessment is based, perform specified controls, and document any complaints and/or appeals and the correction of deficiencies.

The customer must advise DNV MEDCERT without delay of any reportable incident, any field corrective action and of any field safety corrective action undertaken in a third country in relation to the products covered by the certification.

DNV MEDCERT archives all documents and reports for a period of 20 years beyond the validity of a certificate.

The customer is allowed to show DNV MEDCERT´s certification seal in addition to the CE mark. The CE mark may be changed only in accordance with the Medical Device Regulation (EU) 2017/745, Annex V, any change of the DNV MEDCERT certification seal in colour or appearance must be authorized by us.

DNV MEDCERT gives its customers due notice of any changes to the requirements for certification and or conformity assessment.

8 Re-Certification

DNV MEDCERT has in place procedures relating to re-certification processes and assessments and the renewal of certificates. Re-certification of approved quality management systems shall occur at least every 3 years; re-certification of any conformity assessment certificates according to the Medical Device Regulation (EU) 2017/745 at least every 5 years. For EU Technical Documentation Assessment Certificates according to Medical Device Regulation (EU), Annex IX, Chapter II, DNV MEDCERT requires from the customer to submit annually a summary of changes and scientific findings for the products certified, including:

- All changes to the originally approved device, including changes not yet notified
- Experience gained from post-market surveillance
- Experience from risk management
- Experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I
- Experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF
- Changes to the requirements, to components of the device or to the scientific or regulatory environment
- Changes to applied or new harmonised standards, CS or equivalent documents, and
- Changes in medical, scientific and technical knowledge, such as ▸
  - New treatments
  - Changes in test methods
  - New scientific findings on materials and components, including findings on their biocompatibility
  - Experience from studies on comparable devices
  - Data from registers and registries
  - Experience from clinical investigations with comparable devices
- Changes in name and/or address of the customer

9 Changes and Modifications

DNV MEDCERT has procedures and contractual arrangements in place regarding the obligations of the customer to inform us about:

- The approved quality management system or systems or to the product-range covered
- The approved design of a device
- The intended use or claims made for a device
- The approved type of a device, and
- Any substance incorporated in or utilized for the manufacturing of a device and being subject to the specific procedures (e.g. medicinal product, animal tissue)

The procedures and contractual arrangements referred to in the first paragraph include measures for the assessment regarding the significance of the changes.

In accordance with our procedures, we ▸

- Ensure that customer submit for prior approval plans for changes as referred to in the first paragraph and relevant information relating to such changes
- Assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of the medical device regulation (EU) 2017/745, and
- Notify the customer of our decision and provide a report or, as applicable, a supplement to a report, which contains the justified conclusions of our assessment.

10 Exchange of information with recognizing regulatory authorities

When acting as Auditing Organization in the Medical Device Single Audit Program (MDSAP), DNV MEDCERT is obliged to comply with requirements to exchange information with the recognising regulatory authorities (MDSAP participating Regulatory Authorities). This specifically includes obligations of IMDRF "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition (IMDRF/MDSAP WG/N3) and of the current MDSAP policies and procedures applying to Auditing Organizations. By submitting its application for audit under MDSAP, the customer understands and agrees that any information contained in its certification files may be disclosed to recognizing regulatory authorities, if this is warranted by MDSAP program requirements. The recognising authorities may use customer's information in accordance with their juristictional regulations, upon which DNV MEDCERT cannot exercise influence. Especially the following information about the customer may be considered as non-confidential and exchanged: the fact of customer's participation in the MDSAP program and all information included in the customer's MDSAP certificate. Information considered as non-confidential may be published or openly shared by the recognising authorities, for example with other regulatory authorities such as MDSAP Affiliate Members.