# Quality Manual

## Realization of Certification of QM System and Conformity Assessment of Medical Devices

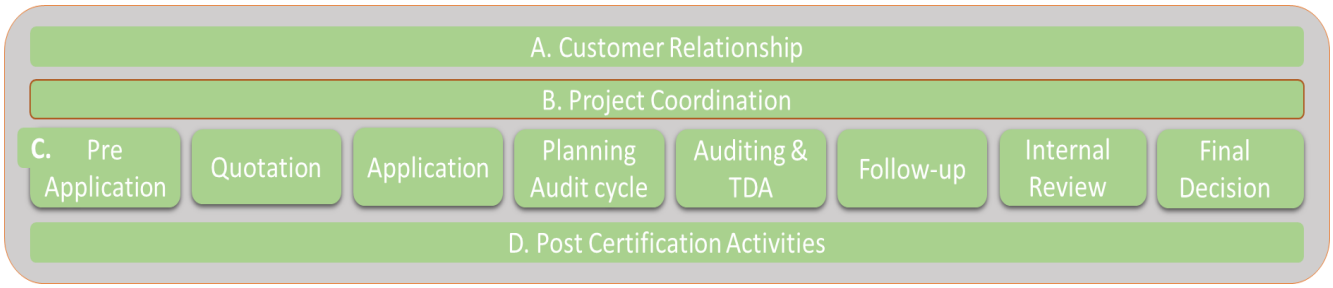
**CONTENT**

The services of DNV MEDCERT are the certification and conformity assessment of quality management systems and medical devices in accordance with regulations and statutory provisions, recognized standards and their guidelines.

The process of certification and conformity assessment follows various process steps independent of whether it is a service based on the Regulation (EU) 20177/745 or on applicable quality system standards, or specific audit models (e.g. MDSAP, TCP Taiwan).

In the following figure, principles of the proceedings within the projects for certification and conformity assessments are described.

For each step detailed SOPs are implemented, established and maintained. They are illustrated below:




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

## A. CUSTOMER RELATIONSHIP

The following description of the requirements for the certification of QM systems and conformity assessments of Medical Devices shall facilitate the customer relationship and communication, so that the process steps are clarified and understood before, during and after the certification projects.

### ➢ 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 external personnel performing these activities are disclosed to the customer. Depending on need, DNV MEDCERT may appoint an external expert 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, or laboratory) 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.

### ➢ Customer Communication

DNV MEDCERT proactively organises and offers the possibility (requested by customer) to conduct structured dialogue where this is useful to enhance the efficiency and predictability of the conformity assessment process.

Structured dialogue aims to clarify and create equal understanding of regulatory aspects, procedural aspects and time-related issues. In this context and depending on the topic to be discussed, virtual or on-site meetings can be conducted. Any details for meetings are clarified customer specific.

The required information and documentation that is needed from the customer, for instance application form, is communicated by applicable questionaires available on the DNV MEDCERT homepage.

### ➢ Exchange of Customer Information with Regulatory Authorities

By submitting its application towards DNV MEDCERT, the customer agrees that any information contained in its certification files may be disclosed by any relevant accreditation body or certification scheme owner (e.g.

MDSAP recognizing authorities), any competent court, governmental agency, or other relevant public authority in accordance with applicable law, court order or other public regulation.

Further details are determined by the general order and payment conditions.

### ➢ Customer Complaints and Appeals

The customer has the right to issue a complaint and/or appeal during projects and against the decision of DNV MEDCERT. The corresponding procedure “Complaints and Appeals” describes the process and is available from the DNV MEDCERT homepage under Download.

DNV MECERT reacts on each written complaint or appeal in a professional manner in order to clarify the situation.

## B. PROJECT COORDINATION

In the phase of pre-application, quotation and application all information of the customer related to such as products, company, locations, persons, scope of certification are collected and evaluated according to the requirements of the MDR. The details are fixed in the corresponding SOPs. In this phase, the department Certification Body is responsible to define the scope of the certification project and to approves the application.

The operation department takes the responsibility to plan the subsequent activities with respect to the approved application according to the related SOPs. Each project and related assigned persons and activities are defined by work orders.

### ➢ Time Limits for Completion of Certification and/or Conformity Assessment Activities

There are no general requirements for the throughput times for completion of certification projects. The complexity of projects, completeness of required documentation, availability of required reviewers and the non-foreseeability of the outcome of a certification process and time needed by the customer to close findings determines the overall duration for finalizing projects. Regular status communication towards the customer clarifies the progress of the activities.

Regulatory time requirements exist for audit duration and concluding of recertification and surveillance audits. There are also requirements of reporting of follow-up activities towards authorities.

### ➢ Changes during and after the Certification Process

It might be requested by the customer, or it was detected during the certification process that changes are required, then a clear communication with respect to the subject of the change has to be ensured.

Changing of following significant subjects requires a change notification (CN) and a review of the impact of these changes to the activities.

- The quality management system or systems or to the product-range covered
- The design of a device
- The intended use or claims made for a device
- The 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 customer has to submit for prior approval plans for changes and relevant information relating to such changes

DNV MEDCERT assesses the changes proposed and verify whether, after these changes, the quality management system, or the safety and performance of the concerned device or type of a device, still meets the requirements.

Finally, the customer is informed about the decision and receives a report or, as applicable, a supplement to a report, which contains the justified conclusions of the assessment.

All decisions related to the change are documented and traceable to the corresponding project, so that all involved staff or external assessors can fully comprehend the result.

### ➢ Process Monitoring

Appropriate data analysis is conducted to follow the progress of projects. Regular review of these data shall ensure that delays of projects are detected and open issues are resolved, in order to continues or to conclude the service activities.

## C. PROCEDURE FLOW OF CERTIFICATION AND CONFORMITY ASSESSMENT

### ➢ Pre-Application and Quotation

The pre-applicaion process starts with the inquiry of a customer to receive a QM systems and product conformity certification.

In order to decide on further activities, the customer is requested to provide information about company, locations, activities per location, products, intended use, suppliers and more specific details that are specified by the DNV MEDCERT questionnaire being available on the DNV MEDCERT homepage.

All inquiries for certification and conformity assessment are reviewed in order to ensure that they are unambiguous and fit with the designated/accredited/recognized scope of DNV MEDCERT. This proceeding applies to inquiries from new as well as inquiries from existing customers. A refusal of the pre-application is also possible.

An initial calculation is prepared and offered to the customer, if all questions are reviewed, clear and sufficient for further process steps. Standard fees are published on the homepage of DNV MEDCERT.

If the inquiry applies to a change of an existing certificate, a quotation will be made only by request. In this case, the invoicing of our services is made according to time and effort.

### ➢ Application

#### a. Certification of a QM System

The customer applies to DNV MEDCERT to perform a certification of the quality management system and/or conformity assessment process. The application form is published on the homepage of DNV MEDCERT.

All documents, as requested and required by DNV MEDCERT 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.

Any open issues during the review, will be clarified to ensure that finally all relevant items are clearly understood.

### b. Conformity Assessment of Medical devices

If the scope of the application also includes a conformity assessment according to the Medical Device Regulation (EU) 2017/745 an assessment of the technical documentation is required. The technical documentation of the concerned medical device according to Annex II of 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.

### c. Transfer of Customers towards DNV MEDCERT

Only customers with valid certificates that are covered by a valid accreditation/designation for MDR, MDSAP and/or ISO 13485 are accepted for a transfer. Within the pre-application review and quotation process the requirements of IAF MD2 are taken into account. Contact is established with the outgoing certification or notified body und the certificate takeover is confirmed with the issue of the certificate. If a transfer procedure is not possible, the customer will be handled as a new customer.

### d. Closure of a Certification Agreement

With every initial application, a certification agreement including the General Order and Payment Conditions is closed directly with the customer and not with any other organisation. This agreement implements the statutory certification and conformity assessment requirements and outlines the responsibilities and duties of the customer and DNV MEDCERT.

## ➢ Planning of the Audit Cycle

Regarding the outcome of the application the relevant certification and conformity assessment activities are planned.

The project coordinator assigned the Lead Auditor and the audit and expert team and creates the work orders accordingly.

## ➢ Auditing and Technical Documentation Assessment (TDA)

### a. Conducting Stage 1 Audits

At the same time as the application the customer must submit the full quality system documention. The lead auditor reviews this documentation for compliance against the requirements. This is a task associated with the stage 1 audit, that can be conducted offsite.

In case of conformity assessment process, DNV MEDCERT pre-assess at least one representative technical documentation. In case the requiremenst are not met, appropriate measures are initiated to close the gaps.

The result is documented in a report and in any case of findings they are documented by nonconformity reports and subsequented follow-up. Open questions can be concluded as onsite part of the stage 1 audit, if appropriate.

The Lead auditor creates from all information reviewed during stage 1 an initial audit programme and associated sampling plan and critical supplier to audit.

## b. Audit Programme, TDA Sampling Plan and Critical Supplier Evaluation

The Lead Auditor has the responsibility to create an audit programme during the stage 1 audit by taking all activities, locations, products, technologies and suppliers into account for the upcoming audit cycle. This audit programme requests additionally a sampling plan for TDA and the evaluation of critical supplier to audit.

The information gained from the application and the stage 1 audit is taken to create a sampling plan for technical documentation assessments and to evaluate the critical supplier status to decide on the risks for involving into the audit programme.

With the final audit programme, it is clear what the scope of the upcoming audits and what the requirements for the audit team will be. The audit programme will be updated after each audit and will be adjusted in any case of changes.

The Lead Auditor completes all tasks of the assessment and documents a recommendation for further proceeding.

If a positive recommendation is given, the Certification Body decides, if a stage 2 audit is possible or not. This is documented in a stage 1 summary.

According to the prepared audit programme all further activities in the context of the QM system certification is planned.

## ➢ Planning and Performance of the System Audit

Regarding the audit programme the stage 2 audit is planned. The audit plan includes the following:

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

The audit plan must be submitted to the applicant duly. This shall enable the applicant to ask for justified changes and to arrange other activities accordingly. It will be finally confirmed during the opening meeting.

The on-site audit is being performed on the basis of the audit plan. 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. The audit team will use checklists and make notes about of their findings.

The rules how to conduct an audit is specified in corresponding process description.

Nonconformities detected during the audit are being recorded and followed up with nonconformity reports.

At the end of the on-site audit, the Lead Auditor provides a verbal summary of the result of the audit and a written audit summary to the customer. The customer receives finalized audit report after concluding certification process after the audit.

The audit report reflects the status of the QM system of the customer, when the audit is finalized. The nonconformities recorded during the audit and being still open at the end of the audit are part of the report and will be taken into consideration for the preliminary recommendation for certification by the Lead Auditor.

The report and associated nonconformity reports are provided to the customer.

## ➢ Technical Documentation Assessment

The assessment of a technical documentation is part of a conformity assessment process for a medical device according to Annex IX and Annex XI of the Medical Device Regulation (EU) 2017/745.

The assessment follows Annex II of the Medical Device Regulation (EU) 2017/745. The conformity of the technical documentation and the product conformity according to Annex I of the MDR are assessed by a qualified reviewer or reviewer team.

An assessment of the clinical evaluation report is always performed.

Depending on the products specific processes may be required to involve competent authorities for the evaluation.

The result of the assessment is documented in a Technical Documentation Assessment report and separated expert reports. They are all provided to the customer after conclusion of the conformity assessment process.

## ➢ Follow-up of Assessment Activities

In case there is any nonconformity related to the quality management system or to the technical documentation assessed, the customer must propose suitable corrections and corrective actions with deadlines for their implementation, including a root cause analysis. The Lead Auditor and/or product reviewer assesses the implemented and/or proposed corrections and corrective actions for their suitability to accept the resolution of each non-conformity. The verification of the result of the correction and/or corrective actions follows the implementation date or at latest during the next surveillance period.

Depending on the complexity of these actions, an additional special on-site audit related to the implementation of the corrective actions may be required.

As far as statements accordingly have not been presented respectively are not acceptable until the requested due date, the procedure to suspend, restrict or refuse the certificate will be initated.

## ➢ Internal Review

The Lead auditor concludes the project by checking the performance and documentation of all relevant topics of the project.

The objective of the subsequent internal and final review is to verify the completeness, traceability and correctness of certification and conformity assessment project from application to the documented audit and technical documentation reports.

Independent staff, that was not involved in any of the activities during the project performs this final review. So, it shall be ensured that the conclusion of all steps of the conformity assessment are clear and demonstrate compliance with the requirements of the applied regulation or standard and can represent objective evidence of such compliance to any persons that were not involved in the assessment.

## ➢ Final Decision and Issue of Certificate

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 decides whether or not the review results lead to the issuing, refusal reduction, extension, suspension or withdrawal of a certificate.

The customer receives a final review report (formerly 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.

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

## D. POST-CERTIFICATION ACTIVITIES

### ➢ Use of DNV MEDCERT Certification Seal

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.

The rules how to use the seal are available on DNV MEDCERT homepage. The seal itself is provided to the customer on request.

### ➢ Customer 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 conformity assessments, 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 situation. The customer will be informed in advance and receive 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 the 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 the designating or recognizing authority. In case of unannounced audits, the customer is not informed prior to the audit. The result of the audit will be summarized in an audit report and submit it to the customer.

The customer is obliged to monitor continuously the performance of certified products according to the requirements on which the assessment was based, perform specified controls, and document any complaints and/or appeals and the corrective actions of deficiencies.

The customer is also oblighed to inform DNV MEDCERT without delay any vigilance reports, any field corrective action including those undertaken in a third country in relation to a device, which is legally made available on the EU market, and co-operate with DNV MEDCERT and the competent authorities during the investigations.

## E. RECERTIFICATION

Recertification of approved quality management systems (ISO 13485) shall occur at least every 3 years.

The validity of QMS certificates (EU quality management system or EU quality assurance certificates) as well as product certificates (EU technical documentation assessment) can be extended for further periods of maximum five years (recertification under MDR). The recertification activities must be completed before expiry of Certificates. Recertifications are not repetitions of initial certifications.

For recertification of product certificates: EU Technical Documentation Assessment Certificates according to Medical Device Regulation (EU), Annex IX, Chapter II, DNV MEDCERT requires customers to submit a summary of changes and scientific findings annually for certified products, including a summary of changes and scientific findings as outlined in MDR Annex VII Section 4.11.

DNV MEDCERT performs a targeted assessment of this information with additional focus on clinical data from post-market surveillance and PMCF activities undertaken, since the previous certification or re-certification including assessment of the appropriate updates of the manufacturers' clinical evaluation reports.

Following applies to recertification of QMS certificates:

- Before the expiry date of QMS certificates, DNV MEDCERT assesses the regulatory requirements for conducting audits in their entirety:
  - Review of the results of all surveillance activities (including, in particular, on-site audits of the manufacturer, its subcontractors/suppliers and product tests carried out, if applicable) carried out during the certification cycle, whether announced or unannounced.
  - (MDR only) results of assessments of the technical documentation on a sample basis to verify that the approved quality management system still complies with the relevant provisions of the MDR.
  - Verification that the audit programme and sampling plan are still up to date or need to be adapted.
- Before renewing of QMS certificates (EU quality management system or EU quality assurance certificates) as well as product certificates, it is verified that
  - all identified nonconformities have either been corrected or are being followed up by an appropriate and accepted corrective and preventive action (CAPA) plan with appropriate deadlines,
  - whether the scope of the certification needs to be adjusted, in particular, whether it needs to be restricted,
  - if the certification was subject to certain conditions or restrictions, whether these are still valid or out of date or need to be changed, or whether new conditions need to be imposed.

Same methods and principles are applied to the decision on recertification as for the initial certification decision.

## F. DOCUMENTATION

All documents and reports from the certification/conformity assesment process are stored and archived in the documentation management system. The requirements are defined in our quality system documentation.

DNV MEDCERT archives all documents and reports for a period of 15 years beyond the validity of a certificate.