# CERTIFICATION PROCESS DESCRIPTION AND REQUIREMENTS

## 1 SERVICE DESCRIPTION

This document describes the DNV Product Assurance AS (DNV) conditions and certification processes for certification to the Medical Devices Regulation – (EU) 2017/745 (MDR) and MDSAP. The document includes relevant elements from the regulation as well as elements from the certification agreement that is the basis for the contractual relationship between the manufacturer and DNV.

Throughout the document when the term DNV as Notified Body is used it also mean DNV as an Auditing Organization under MDSAP.

## 2 LEGAL FRAMEWORK

### Notification

DNV will perform this service as Notified Body in conjunction with MDR. As a Notified Body DNV is designated by The Norwegian Medicines Agency. The designation is registered in the NANDO database with DNV Product Assurance AS, Notified Body ID No.2460.

In the following text DNV shall be understood as the legal unit notified as Notified Body 2460 and all personnel qualified and approved by to provide the service. All final decisions are done at the Notified Body.

### General conditions

- The requirements of the MDR are ultimate.
- The requirements in the general terms and conditions of the standard DNV Certification Agreement (CA) applies
- The Notified Body does not provide any consultancy services including any GAP assessments. The Notified Body can provide guidance in interpreting the MDR including the classification rules, Notified Body processes, Notified Body documents (e.g., The Quotation request from)
- All technical information needed for Notified Body evaluation of the product is treated as confidential.
- The final decision on classification, on rule used, conformity assessment route and fulfilment of the MDR is the responsibility of the manufacturer.
- In case of dispute on classification between manufacturer and Notified Body, matter must be addressed to the Competent Authorities of the Member State where manufacturer or its authorized representative is located.
- Manufacturer when applying to Notified Body must declare whether it has withdrawn an application with another notified body prior to decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.
- Manufacturer, having applied to the Notified Body, may not lodge an application in parallel with another notified body for the same conformity assessment procedure.
- Notified Body may require any information or data from the manufacturer, which is necessary to properly conduct the chosen conformity assessment procedure.

## Language requirements

All technical documentation must be in English, all tests and studies included. The same applies to periodical safety update reports, Summary of safety and clinical performance, vigilance reports (including Incident reports, vigilance reports, field safety corrective actions documents, FSN´s etc.) and change notifications.

The quality system procedures can in general be in local language except for procedures for Risk Management, Clinical Evaluation and Post Market surveillance activities (PMS, PMCF, Vigilance reporting, PSUR – MDR Chapter VII and associated annexes) as well as procedure providing criteria's for when to report a change to the Notified body.

Communication between the manufacturer and the Market Unit may be in Local Language. Communication to the Notified Body shall be in English.

# 3 DNV CERTIFICATION PROCEDURE

The certification process is performed by the Notified Body assisted by appointed Market Units.
The Market Units are authorized to perform certain activities in relation to the application and certification processes.

## Application

A Manufacturer or its Authorized Representative lodges an application for CE marking of medical devices (and/or Quality Management System Certification and/or MDSAP) by filling in a Quotation Request Form (QRF) and submitting it to the Market Unit.

Upon reception of the QRF, the Market Unit will review the enquiry, prepare a Certification proposal, and submit to the Notified Body for review and approval of the quotation.

Upon successful review and approval of the application and the Certification Proposal, by The Notified Body, the Market Unit will send a Certification Agreement (CA) describing all activities, and costs, involved in the certification process.

An authorized person of the manufacturer shall sign and return the Certification Agreement. The certification Agreement shall be concluded directly between DNV as Notified Body and the manufacturer, not any other organization. The Notified Body and the manufacturer have thereby a formal agreement with each other, where the manufacturer also declares that the same application has not been lodged with any other Notified Body. Market Unit co-signs the agreement to fulfil local regulations and/or requirements.

The Notified Body is obliged to report the following to EUDAMED (until EUDAMED is ready, the reporting will be to the national Competent authority):

- Certificates issued, including amendments and supplements
- Certificates suspended, reinstated, withdrawn
- Refused certificates and restrictions imposed on certificates
- Any application withdrawn by the manufacturer prior to decision made by the Notified Body.

MDSAP Specific Requirement:

- Notified Body shall maintain and follow the MDSAP Regulatory Exchange Platform for each manufacturer and for each individual site.

## Certification costs

The manufacturer shall agree to pay all costs related to:

- "Planned" activities (audits, closing of non-conformities, assessments, tests, review of periodical safety update reports etc.)

- Unannounced audit activities at the manufacturer and at subcontractors and suppliers.

Extra activities or revision of the “planned” activities - e.g. Increased surveillance audit frequency, increase of frequency of assessments, requirements for periodical reports if post market data reveals the need (e.g. through feedback from the market, through analysis of incident reports etc), if audit/assessment activities documents that the quality system or the devices are challenged or if there is revision to the regulation or the interpretation of the regulation (e.g. Implementing or delegated acts, common specification, harmonized standards).

Costs and fees with relevant terms are specified in the Certification Agreement (CA).

## Certification activities

Notified Body has the overall responsibility to carry out the Notified Body services in accordance with the regulation, including the certification activities carried out by the Market Units.

All personnel engaged in the assessment activities are qualified as per Notified Body requirements.

The manufacturer agrees to promptly supply to the Notified Body, where duly justified, any relevant information and data, allowing the Notified Body to verify the initial as well as ongoing compliance with the MDR.

The manufacturer will further ensure that the Notified Body, its employees, Market Units, and any others acting on behalf of the Notified Body will get all necessary documentation and data, and access permits to the manufacturer and critical suppliers’ premises – also for doing unannounced activities.

MDSAP Specific Requirement: Notified Body is equally responsible to carry out as an Auditing Organization services in accordance with the MDSAP requirements including the certification activities carried out by the Market Units.

### Assessment of technical documentation (on a sample basis) [not applicable for MDSAP]:

The Notified Body is performing technical file assessments for products in class IIa and IIb (except certain IIb devices) based on a sample plan that is defined by the Notified Body.

The sampling plan ensures that an adequate number of technical files are assessed for compliance. The Sampling plan is not shared with the manufacturer.

The assessments are conducted before the Initial audit (stage 1) and throughout the certification period.

Certain devices require consultation with relevant parties (e.g., Expert Panels established by the Commission), and the assessment will not be considered as completed before the consultation is closed.

Any non-conformities identified as part of the assessment must be closed in less than 3 rounds. If the technical file assessment is made in relation to a certification, scope extension or a re-certification, nonconformities need to be closed out, before certificate can be issued.

### Assessment of technical documentation (non-sample basis) [ not applicable for MDSAP]:

All class III devices and certain IIb devices are not subject to technical file assessment based on a sampling regime – a full assessment of compliance is needed for every device to be certified.

A separate certificate covering the devices is issued with a maximum validity of 5 years.

Certain devices require consultation with relevant parties e.g., EMA, competent authorities, Expert Panels established by the commission and the assessment will not be considered as completed before the consultation is closed.

Any non-conformities identified as part of the assessment must be closed in less than 3 rounds. If the technical file assessment is made in relation to a certification, scope extension or recertification, nonconformities need to be closed out before certification can be issued.

## Initial Audit, Stage 1:

Stage 1 audit includes:

- Pre-assessment of the quality system to the requested certifications and requested scopes (May also be off-site, before the on-site audit)
- On-site audit to verify:
    - That the information upon which the Notified Body has planned the audit is correct (i.e., conduction of the planned process will lead to a certification)
    - That Notified Body has allocated the right resources and time for the certification audit
    - That manufacturer is ready for a certification audit
    - Any need for supplier audits

Any findings identified during Stage 1, shall be solved by the manufacturer before the Stage 2 of the initial audit.

If the conclusion of the stage 1 audit is negative, then the stage 2 audit will be on hold until a successful stage 1 audit has been completed with success.

The Stage 1 activities may call for a revision of the Certification agreement and/or costs related to the certification.

MDSAP Specific Requirements:

- Findings from any prior audit shall be used when grading NCs identified at a subsequent regulatory audit.
- Following MDR, under MDSAP, none of the following services can be provided: mock audits, gap audits or pre-assessment audits outside of the scope of Stage 1/Stage 2 audits.
- Elements of Stage 1 and Stage 2 may be combined to allow for a single on-site audit.
- Planning shall ensure Stage 1 objectives shall be met.

## Initial audit, Stage 2 (also known as a Certification audit)

The certification audit will include all the quality system requirements per the selected certifications and certification scopes.

If a need for audit of significant suppliers is identified, the audit of these is a Stage 2 activity.

In relation to devices in class IIa, IIb and III it is noted that this activity (initial audit, Stage 2) shall not be initiated before the technical documentation has been assessed (see later paragraphs).

All Major Nonconformities identified during stage 2 audit shall be closed out within 90 days and Minor Nonconformities shall be implemented without any undue delay.

The certification cannot be granted before all major nonconformities identified during assessment of technical documentation or as part of the audit activities have been successfully closed out.

MDSAP Specific Requirements:

- All sites that will be recorded on the certificate shall be audited. Any sites which are relevant to the manufacturer's quality management system but audited off-site, should not be recorded on the certificate.
- Stage 2 audit objectives shall be met.

## Issuing of Certificate

When all assessment activities are completed successfully, the documentation is subject to technical review (“Final control” of the documentation being the basis for the certificate). Any findings made as part of this process will need to be addressed before the certificate can be issued. The process that may require involvement of the manufacturer (Corrective actions, revision of documentation, additional documentation etc.)

Once the technical review is complete and any findings have been resolved, the certificate(s) can be issued.

Certificates are normally issued with duration of 5 years, however the Notified Body may, in certain situations, issue with a shorter duration.

MDSAP Specific Requirements:

- MDSAP Certificate has a maximum validity of 3 years.

# MAINTAINING CERTIFICATION

The manufacturer must always, when certified, ensure that the requirement of the regulation is fulfilled.

The Notified Body will assess the compliance of the manufacturer as listed in surveillance activities, recertification activities and as it may be required to verify compliance - e.g., in case of a new harmonized standard, new Common Specifications or the publication of an Implementation or Delegated Act.

## Periodical activities

### Audits

After the Initial audit (Stage 2), periodical audits will be conducted to verify that the quality system remains effectively implemented – this will be as agreed between the manufacturer and the Notified Body, however at least every 12 months. Periodical supplier audits may be required.

MDSAP Specific Requirements:

Surveillance audits shall include a review of issues related to medical device safety and effectiveness since the last audit such as complaints, problem reports, vigilance reports, and recalls/field corrections/advisory notices.

Unannounced audits will be conducted as required by the MDR.

MDSAP Specific Requirements:

- Triggering criteria for unannounced audits is based on previous audit findings that indicate serious / frequent nonconformities such as one or more Grade 5, or more than two Grade 4 nonconformities, when using GHTF/SG3/N19:2012. The timing, allowance for the implementation of corrective actions, focus and resource requirements of the unannounced audit are to meet the requirements defined in this clause
- Triggering criteria: specific information provides a reason to suspect serious nonconformities of devices, or their manufacturer, or if requested by an RA. Focus is on the specific information or the substance of the request from the RA.
- When the Notified Body performs a special audit at the request of the RA(s), or an unannounced audit shall submit the audit report to the RA(s) within 15 days from the last day of the audit.

For audits, All Major non-conformities shall be closed out within 90 days (unless the Notified Body decides otherwise based on the nature of the non-conformity) and Minor non-conformities shall be closed out according to the plan agreed with the Notified Body

MDSAP Specific Requirements:

Last day of the audit is defined as D0, from that day the below timeline is followed - MDSAP AU P0027.005 Post Audit Activities and Timeline Policy:

- D0+5 - For the Auditing Organization to provide the Regulatory Authorities with early awareness communication (MDSAP 5-day Notice) and the complete Audit Report Package.
- D0+15 - days for the manufacturer to provide the Auditing Organization with the results of their investigation of any nonconformity, the correction and corrective action plans, and the evidence of implementation of these actions.
- D0+30 - calendar days: Recommended due date for the manufacturer to provide evidence of implementation of the remediation actions addressing any grade 4 or 5 nonconformity
- D0+45 calendar days: Due date for the Auditing Organization to provide the complete audit report package if the audit meets the criteria for an MDSAP 5-day Notice.
- D0+90 calendar days: Due date for the Auditing Organization to provide the complete audit report package if the audit does not meet the criteria for an MDSAP 5-day Notice.

### Assessment of technical documentation (on a sample basis)

Technical documentation assessment will be performed, during the certification period - as per the Sample plan established by the Notified Body.

All non-conformities shall be closed out within 90 days (unless the Notified Body decides otherwise based on the nature of the non-conformity) and with max. 3 iterations.

### Assessment of technical documentation (Non sample basis):

Post-market surveillance data assessment will be performed. This includes, but not limited to verification of the Periodic Safety Update Reports, Summary of Safety and Clinical Performance.

All non-conformities shall be closed out within 90 days (unless the Notified Body decides otherwise based on the nature of the non-conformity) and with max. 3 iterations.

## Recertification activities

### Audits

The audit 5 year after the Initial audit (Stage 2) is a recertification audit. The Recertification audit will cover all elements of the regulation and the quality system for verifying the implementation and the integrity of the system or the selected certification scope.

Supplier audits may be required.

All Major non-conformities shall be closed out within 90 days (unless the Notified Body decides otherwise based on the nature of the non-conformity) and Minor non-conformities shall be closed out according to the plan agreed with Notified Body.

Upon successful completing the audit and assessment activities, the certificates will be reissued.

Technical file assessments, on a sample basis or on a non-sample basis shall be performed as specified in relation to recertification activities.

MDSAP Specific Requirements:

- The audit shall be 3 years after the initial audit (stage 2) is an MDSAP Recertification Audit. All sites that are recorded on the certificate shall be audited. Any sites which are relevant to the manufacturer's quality management system but audited off-site, should not be recorded on the certificate.
- Recertification Audit objectives shall be met.
- Includes a review of previous surveillance audit reports and the performance of the QMS over the most recent certification cycle.
- Notified Body shall schedule recertification audits with sufficient time to complete the recertification process prior to the end of the certificate period. It is not acceptable to have an expired certificate as described in ISO/IEC 17021:2015 Clause 9.6.3.2.5.

### Assessment of technical documentation (on a sample basis):

Assessment of technical documentation, on a sample basis is performed as specified in the sampling plan.

All non-conformities shall be closed out within 90 days (unless the Notified Body decides otherwise based on the nature of the non-conformity) and with max. 3 iterations.

### Assessment of technical documentation (non-sample basis):

An Assessment of technical documentation shall be performed for all devices certified, based on updated technical documentation and documentation detailing the changes since the initial certification. The process is the same as for the initial assessment for certification.

All non-conformities shall be closed out within 90 days (unless the Notified Body decides otherwise based on the nature of the non-conformity).

Upon successful completing the audits and assessment activities, including technical review, the certificates will be reissued.

MDSAP Specific Requirements for Technical Documentation.

- Onsite audits such as stage 2, surveillance, recertification include evaluation of the effectiveness of the manufacturer's quality management system (QMS) as well as aspects of evaluation, including:
- product/process related technologies (e.g., injection moulding, sterilization); and,
- evidence of adequate product technical documentation in relation to relevant regulatory requirements. To the extent possible during on-site audits in accordance with the applicable regulatory system.

## REFUSAL OF CERTIFICATION

Certification shall be refused if devices or the quality system is found not to comply with MDR and MDSAP, when the device is found not to be a medical device and for other conditions given in the regulatory agreement.

The Notified Body shall communicate refusal of certification to the applicant in writing and the communication shall include information that the decision may be appealed.

The Notified Body is required to report refusal of certification in EUDAMED (Article 53 of the MDR)- information on refusal will be accessible to other notified bodies.

The manufacturer may, once the contractual relations with the Notified Body has been terminated, decide to apply for certification with another notified body. The manufacturer is obliged to inform the other Notified body of the refusal.

## CHANGES IN REGULATION/REGULATORY ENVIRONMENT

The Notified Body will assess the products subject to certification to the valid versions of the regulatory requirements. Changes in standards, common specifications, best practice guidelines and additions of implementing/delegated acts may result in the need of re-assessing devices and quality systems before the expiry date given on the certificate.

The manufacturer is obliged to stay current on the formal status of the regulatory requirements as well as standards that he has applied.

## WITHDRAWAL OF APPLICATION

In case the manufacturer decides to withdraw the application for conformity assessment, the Notified Body will report this in EUDAMED (Article 57 of the MDR)- information on withdrawal will be accessible to other notified bodies.

The manufacturer may, once the application has been withdrawn, decide to apply for a certification with another Notified Body. The manufacturer is obliged to inform that Notified Body that they have withdrawn the application.
MDSAP Specific Requirements:

- Communicate to the Regulatory Authorities as described in MDR-CP-174 Communication with Authorities for the following activities: Refusal of certification, Withdrawal of application, Changes by manufacturer.

## CHANGES BY MANUFACTURER

Manufacturer must report all changes regarding the devices and the approved quality system as per the requirements of the regulation (Incl. changes in the organization, ownership, new products, modifications to the production method and quality system, site locations etc.). Changes reported to the Notified Body shall not be implemented before the Notified Body has accepted the changes.

It will be the decision of the Notified Body whether there are additional activities required before the change can be accepted – this includes on-site extra audits, document review, evaluation of technical documentation etc.

MDSAP Specific Requirements:

- Communicate to the Regulatory Authorities for the following activities: Refusal of certification, Withdrawal of application, Changes by manufacturer, Suspension, scope reduction of certification by the manufacturer.

## SUSPENSION, SCOPE REDUCTION AND WITHDRAWAL OF CERTIFICATES

The Notified Body may decide to suspend or withdraw the certificate, and, in such cases, the manufacturer will be informed as soon as this is practicable. The impact of these actions is:

- Suspension – Time-limited invalidation
- Withdrawal – Permanent invalidation.
- Scope reduction – Partial Suspension or withdrawal of certificate.

The Notified Body will contact the manufacturer to have the situation leading to actions toward the certificate resolved before the action is decided – this does not apply in case the cause of the suspension/withdrawal may lead to unacceptable risks to patients if there is an unacceptable risk/benefit ratio or in case of significant lack of compliance with the requirements.

Decisions taken by the Notified Body may be appealed by the manufacturer.

MDSAP Specific Requirements:

- Communicate to the Regulatory Authorities for the following activities: Refusal of certification, Withdrawal of application, Changes by manufacturer, Suspension, scope reduction of certification by the manufacturer.

## Suspension

The Notified Body may suspend certification if the certification agreement conditions and if the requirements of the MDR is not complied with – this includes:

- The certificate is being misused.
- The requirements as set out in the regulation on which the conformity assessment procedure has been based and which form the basis for issuing the certificate or the appendix, were not fulfilled.
- The device was incorrectly defined as device per the regulation.
- The device-range covered by the certifications has been changed, or the devices has been significantly changed, without prior accept by the Notified Body. Class III and IIb all changes shall be accepted by the Notified Body before implementation.
- The approved the quality management system has been substantially changed system without the Notified Body acceptance before implementation.
- The requirements to the quality system are no longer fulfilled.
- The product is no longer covered by the regulation or is to be different classified due to Implementing act/delegated act etc.
- The device is no longer in compliance with the regulation and the non-conformities shortcomings observed are not corrected by the manufacturer within an appropriate period as defined by the Notified Body under consideration of the severity and potential impacts of these shortcomings. (The latter does not apply in case of unacceptable risks to patients or an unacceptable risk/benefit ratio).
- Violation of the terms of the signed certification agreement, including non-payment of fees or refusal of access to unexpected/periodic/planned assessments.
- Scheduled activities, including assessments and audits, cannot be conducted.
- Manufacturer voluntarily requesting temporary suspension.
- Not closing non-conformities within the timelines given
- Preventing unannounced audits will lead to immediate suspension.

Suspension of a certificate is normally initiated as the first step, followed by a withdrawal if the issue of concern is not resolved, by the manufacturer, in due time. However, depending on the seriousness of the situation, the Notified Body may decide a direct withdrawal of the certificate. Certificate suspensions are normally limited to 3 months.

The Notified Body shall inform the manufacturer about the decision on suspension and that no devices can be put on the marked during the suspension period.

The manufacturer shall delete any reference to a non-valid EU certificate in public documentation like marketing material, websites, advertising etc.

The Notified Body shall update the certificate status in EUDAMED.

MDSAP Specific Requirements:

- Communicate to the Regulatory Authorities for the following activities: Refusal of certification, Withdrawal of application, Changes by manufacturer, Suspension, scope reduction of certification by the manufacturer.

## Withdrawal

The Notified Body may withdraw certification when:

- The reason for a suspension has not been resolved within the time limits set for the case.
- The quality management system has not been followed during the suspension period
- Surveillance has not been performed over the suspension period
- Manufacturer has not allowed (or provided documentation) the Notified Body to conduct further conformity assessments activities.
- Any other reason giving doubt to the compliance of the company

Withdrawal is initiated if the reason for a suspension is not resolved in time or if the Notified Body finds that the situation requires a withdrawal for the certificate. The manufacturer is given appropriate warning and possibility to solve the issue, before the withdrawal is executed, if it does not lead to unacceptable risks to patients or an unacceptable risk/benefit ratio.

The manufacturer shall delete any reference to a non-valid EU certificate in public documentation like marketing material, websites, advertising etc.

The Notified Body shall update the certificate status in EUDAMED.

MDSAP Specific Requirements:

- Communicate to the Regulatory Authorities for the following activities: Refusal of certification, Withdrawal of application, Changes by manufacturer, Suspension, scope reduction of certification by the manufacturer.

# CANCELLATION OF CERTIFICATION BY MANUFACTURER

The manufacturer may cancel the certificate at any time provided that the Notified Body receives a written communication at least 60 days before the wished cancellation date authorizing the Notified Body to invoice all activities up to that date.

MDSAP Specific Requirements:

- Communicate to the Regulatory Authorities for the following activities: Refusal of certification, Withdrawal of application, Changes by manufacturer, Suspension, scope reduction of certification by the manufacturer.

# COMPLAINTS AND APPEALS

Complaint is understood as a statement of dissatisfaction from the manufacturer about the Notified Body certification activities.

Appeal is understood as an objection from the manufacturer to a specific decision taken by the Notified Body.

## Filing of a complaint or appeal

The Notified Body will handle any complaints and appeals.

The Notified Body request that the following information is provided in relation to the complaint:

- Company name, address, and SRN.
- Reference to service, office, area, etc.
- Identification of the specific decision which is subject to the appeal.

- If the contested decision is related to a valid or expired certificate, then the certificate number shall be identified.
- The reason for the complaint or appeal and which modification of the case processing or decision made is requested as outcome of the process.
- Identification of which precise supportive evidence supports the appeal and explanation why the submitted supportive evidence is relevant.
- Reference to and copy of the contract applicable to the decision subject to the appeal or complaint.
- Contact person and details for the further communication about the complaint or appeal, including contact person's authorization to act on behalf on behalf of the company

## Initial handling and actions taken

Upon receipt of a complaint or an appeal the Notified Body will take the following actions:

- The complaint/appeal will be logged in our system
- A person responsible for the complaint/appeal handling will be appointed
- An initial response to the complainant/appellant will be sent within 10 working days

The person responsible for handling the complaint/appeal will evaluate if immediate actions and/or corrective actions are needed. This person shall have no previous involvement in the concerned certification.

## Written resolution

A written response to the complainant/appellant will be prepared and submitted. The complainant/appellant will be informed about the right to escalate the complaint/appeal in case the response is not satisfactory.

## USE OF CE MARK

The Manufacturer shall have the right to use the valid certificate for the purposes for which such certificates are generally intended and used, including on letters, documents, and other promotional material. The indication of being certified shall be clear and not misleading in any way.

The CE mark shall only be as described in the MDR.

Manufacturers certificated may refer CE 2460 mark in brochures, flyers, fact sheets or on the home page to show that they are certified. The use shall not be misleading.

## USE OF MDSAP CERTIFICATES AND AUDIT REPORTS

- MDSAP issued certificates and reports shall meet the Regulatory Authority requirements.
- Limitation of the usage of the MDSAP LOGO and cannot be used on commercialized goods.
- Manufacturers shall communicate with the MDSAP Regulatory Authorities within 30 days of any changes / revisions to the MDSAP Certificate [example Health Canada].
- MDSAP issued certificates and reports intended for use by a specific Regulatory Authority, they shall accurately document the scope of the audits, audit criteria and the scope of the certifications, including which Regulatory Authority requirements have been assessed. Notified Body shall not exclude any processes, products, or services from the audit scope or the scope of the certificate, unless the regulations administered by the recognizing Regulatory Authority(s) permit the exclusion.