DNV GL management system

ICP – Product Certification

ICP 4-6-3-5-CR

Document number:	Valid for:	Revision:	Date:
ICP 4-6-3-5-CR	All in DNV GL	4	2020-04-14
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Revisions in this document:

Rev. no.	Date	Description of revision
4	2020-04-14	Change of Notify Body nr from 0434 to 2460
3	2019-03-06	Notification scope changed and Quality Policy added
2	2017-05-05	Notification scope changed and Quality Policy added

1 SERVICE DESCRIPTION

This document describes the DNV GL conditions and certification processes for certification to the Machinery Directive 2006/42/EC (MD). The document defines Customer and DNV GL obligations additional to the Terms and Conditions in the Product Certification Agreement between the parties and in the Annex to the certificate.

Following the definitions in MD the Customer will in the following be referred to as the Manufacturer. The Manufacturer is responsible for designing and manufacturing a product intended to be placed on the European market.

2 LEGAL FRAMEWORK

2.1 Notification

DNV GL will perform this service as Notified Body in conjunction with MD. As a Notified Body DNV GL is also committed to the DNV GL purpose, vision and values.

DNV GL is notified by The Norwegian Labour Inspection Authority (NO: "Arbeidstilsynet"). The notification is registered in the NANDO database with Notified Body ID No. 2460. In its role as a Notified Body, DNV GL is subject to the Norwegian Notified Body legislation and is executing authority tasks under the Norwegian Public Administration Act and the Public Information Act. The notification scope is:

Products:

- MD Annex IV:17 (Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres).

Conformity assessment procedures:

- Annex IX (EC Type Examination), and
- Annex X: (Full Quality Assurance)

The Norwegian Lov om Tekniske Kontrollorgan (Act on Notified Bodies, "TKO") § 5 states that Chapters II–VI of the Norwegian Public Administration Act (PAA) applies to conformity assessments made by the Notified Body. The provisions in the PAA only concerns execution of the conformity assessment procedures in Annex IX and X of the MD. The following parts of the PAA are applicable:

- Integrity/impartiality requirements in Section 6.
- Confidentiality requirements in Section 13.
- Guidance requirements in Section 11.
- Notice on Certification decisions in Section 16
- Appeal of certification decisions in Chapter IV

The above requirements are covered by this document, the Business Assurance global procedures and the MD customer agreements.

In the following text DNV GL shall be understood as the legal unit notified as Notified Body 0434 and personnel in all DNV GL units qualified and approved by to provide the service. The final certification is done at the Notified Body uniquely.

2.2 Quality Policy

The DNV GL Quality Policy is developed by the DNV GL Group management. The document is applicable for all services in DNV GL, including Notified Body services:

DNV GL's ambition is to have a leading position in all industries where we operate whilst never compromising on integrity and quality.

We commit ourselves to:

- *Deliver in accordance with stakeholders' expectations*
- *Continually improve our performance*

This is achieved through:

- *Serving our customers with a high degree of pro-activeness and responsiveness*
- *Complying with applicable standards and regulations*
- *Continually improving our services*
- *Continually improving our management system*
- *Continually investing in research and innovation*
- *Striving to be at the forefront of technology*
- *Striving to attract, develop and retain leading competence*

The quality policy is available for downloading at our external webpage.

3 GENERAL CONDITIONS

In addition to the general terms and conditions of the standard DNV GL Product Certification Agreement (PCA), the following applies:

The certification will state compliance of the product to the relevant parts of the MD Annex I Essential Health and Safety Requirements (EHSR). The standards used by the manufacturer in order to achieve this will be listed on the certificate.

The legislation relevant to the product(s) is the MD, which is transferred to national legislation in all European Economic Area (EEA) member states.

If the requirements in MD do not provide sufficient guidance for evaluating the product the official MD Guidelines will be applied in first hand.

DNV GL will not provide any consultancy services aiming to facilitate the design or construction of the product.

All product information needed for the DNV GL evaluation of the product is treated as confidential.

4 DNV GL CERTIFICATION PROCEDURES

4.1 Application

Upon reception of a Request for Quotation (RFQ) sent by a manufacturer, DNV GL will draw up a Product Certification Agreement (PCA) describing all activities involved in the certification process connected to price. The formal application for certification is annexed to the PCA. An authorized representative of the manufacturer shall sign and return both documents. By completing and signing both documents the manufacturer and the Notified Body have a formal agreement with each other where the manufacturer also declares that the same application has not been lodged with any other Notified Body.

A manufacturer of non-Annex IV products may also apply for voluntary certification. In these cases, DNV GL will follow the same Certification procedures as for products under the notification scope, but the services will not be carried out as Notified Body services. No references will be made to the Notified Body 0434 in any deliveries to the customer, and the manufacturer may not refer to DNV GL as a Notified Body. The certificate shall not be referred to in the manufacturer's Declaration of Conformity.

4.2 Activities

DNV GL has the overall responsibility to carry out the Notified Body services in accordance with the regulation given by the legal Norwegian authorities. This also includes the work carried out by the Local DNV GL Units approved by the Notified Body.

Personnel engaged in the assessment activities shall fulfil the requirements as defined by DNV GL.

The manufacturer agrees to promptly supply to DNV GL, where duly justified, any relevant information data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

The manufacturer will further ensure that DNV GL, its employees and any others acting on behalf of DNV GL will get all necessary work and access permits.

4.3 Issuing of Certificate

When all assessment activities are completed, the Local Unit will store all records and correspondence, including results from the assessment activities and their main conclusions in the production tool and then call for a Technical Review at the Notified Body.

The Technical Reviewer will either accept the documentation or require additional information from the Local Unit.

The project is ready for Certificate issuance when the project file is found satisfactory by the Notified Body and all corrective actions for non-conformities are accepted. The conditions for handling of findings will be detailed in the audit report/inspection report. DNV GL will issue all formal documents and certificates according DNV GL's notification (see chapter 2 of this document).

DNV GL is obliged to keep the Technical File for the product(s) for 15 years from the date of issue of a certificate. When a certificate is renewed, the Technical File shall be kept for 15 years from the renewal date.

EC Type-examination certificates will be issued with a validity period of 5 years from date of issuance when the product(s) is (are) intended for serial production. For products not intended for series manufacture, the certificates will be valid for the examined product(s) only.

The validity period and retention period for technical file stated above also applies to Type-examination certificates issued for non-Annex IV products.

The manufacturer is obliged to keep the Technical File for the product(s) at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

For Full Quality Assurance the Certificate is renewed every three years under surveillance by at least two DNV GL periodic audits under the validity period.

5 REFUSAL OF CERTIFICATION

Certification shall be refused if the product or the quality system is found not to comply with MD.

DNV GL shall communicate refusal of certification to the applicant in writing. DNV GL shall provide the possibility for appeals against its decisions. See part 11 of this document.

DNV GL shall make relevant information regarding the certification it has refused available to other MD Notified bodies and the appropriate national authorities.

6 MAINTAINING THE CERTIFICATE

The validity period for MD certificates are stated under 4.3 in this document. The manufacturer must at all time during this period ensure that the requirements of the standards under the certification scope are complied with. The fees as stipulated in the PCA must be paid following the conditions for payment stated therein.

For EC-Type Examination DNV GL will inform the manufacturer of any major changes affecting the validity of the certificate. If the manufacturer wishes to keep the Certificate valid after five years, it is the manufacturer's responsibility to request DNV GL to review the validity of the Certificate. If the validity is confirmed by the review, the Certificate will be revised and valid for another five years.

For Full Quality Assurance the manufacturer is obliged to maintain its certified quality system approved and certified by DNV GL. DNV GL will assess the validity of the quality system by scheduled yearly periodic audits during the validity period. Corrective actions to identified findings must be implemented within the set time limit. The manufacturer shall further authorize DNV GL to pay unannounced visits to the manufacturer's premises when foreseen by the directive or due to reasonably substantiated doubts regarding the compliance of the product or the appropriate functioning of the approved quality system. The manufacturer is also obliged to keep a record of all complaints concerning the products under the

certification scope with regard to the standard requirements. DNV GL will verify that the manufacturer has taken relevant corrective actions for these complaints in conjunction with the surveillance visits.

7 CHANGES IN STANDARD

DNV GL will assess the products subject to certification to the valid versions of the standards applied by the manufacturer unless otherwise agreed. Changes in standards may result in the need of re-assessing type-examined products before the expiry date given on the certificate. The manufacturer is obliged to stay current on the formal status of the standards that he has applied and is responsible that his products are complying with the valid version of the standard.

8 CHANGES BY MANUFACTURER

Manufacturer must report all changes with regard to design and/or production (hereunder changes in the organisation, ownership, new products, modifications to the production method and quality system, site locations etc.), which may reasonably be considered to have an effect of the certified product(s), to DNV GL within a reasonable time and before execution of such change. Failure to do so may result in a non-compliance being raised by DNV GL.

It will be the decision of DNV GL whether or not a further inspection visit or audit is necessary at the time of the announcement of any such changes.

9 SUSPENSION OR WITHDRAWAL OF THE CERTIFICATE

DNV GL 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 are:

Suspension – Time-limited invalidation

Withdrawal – Permanent invalidation

DNV GL shall provide the possibility for appeals against its decisions. See part 11 of this document.

9.1 Reasons for suspension

- The certificate is being misused
- The requirements as set out in the Directive 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 product was incorrectly defined as machiney according to the Directive
- The product is changed and the manufacturer has not informed DNV GL about it
- The requirements for the quality system or the machinery are no longer fulfilled
- The product is no longer covered by the Directive
- The machinery is no longer in compliance with the Directive, and the shortcomings observed are not corrected by the manufacturer within an appropriate time period as defined by DNV GL under consideration of the severeness and potential impacts of these shortcomings.
- Violation of the terms of the signed certification agreement, including non-payment of fees or refusal of access to unexpected/periodic/planned assessments.

- Scheduled assessments not completed.
- Customer voluntarily requesting temporary suspension.
- Incorrect use of the certification mark.
- Information from stakeholders that could affect the status of certificate (e.g. non-compliance to regulatory/statutory requirements).

Suspension of a certificate is normally initiated as the first step, followed by a withdrawal if the issue of concern is not resolved within due time. However, depending on the seriousness of the situation, DNV GL may decide a direct withdrawal of the certificate.

DNV GL shall inform the customer about the decision on suspension and that no products are allowed to be put on the marked during the suspension period.

The manufacturer must delete any reference to a non-valid MD certificate in public documentation like marketing material, web-sites, advertising etc.

DNV GL shall make relevant information regarding the certification it has withdrawn available to the other Notified Bodies and the appropriate national authorities.

A certificate shall generally not be suspended for more than three months, where the case should either be resolved, and the Certificate reissued, or should be escalated to a withdrawal process.

9.2 Reasons for withdrawal

- The issues that resulted in a suspension has not been resolved within the time limits set for the case
- A suspension is not found appropriate
- The holder of the Certificate asks for withdrawal

Non-conforming situations leading to suspension or withdrawal of a certificate shall be identified using the non-conformity process. An exception to this is delay or refusal to pay due fees or refusal of access to premises for the purpose of performing assessments.

DNV GL shall inform its notifying authority concerning the certificates which it has issued or withdrawn and shall, periodically or upon request, make available to its notifying authorities the list of certificates refused, suspended or otherwise restricted.

10 CANCELLING OF THE CERTIFICATE FROM THE MANUFACTURER

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

11 COMPLAINTS AND APPEALS

Complaint is understood as a statement of dissatisfaction from the manufacturer with regard to the DNV GL certification activities.
Appeal is understood as an objection from the manufacturer to a specific decision taken by DNV GL.

11.1 Filling of a complaint or appeal

In order to improve traceability and effectiveness of the handling of complaints and appeals they should be submitted in written form. The following information is then required:

- Identification of the complainant/appellant through company name (if any) and contact person
- Postal address and e-mail address
- Description of the circumstances, including reference to relevant documentation

11.2 Initial handling and actions taken

Upon receival of a complaint or an appeal DNV GL will take the following actions:

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

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

11.3 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.

12 USE OF THE CERTIFICATE (THE DNV GL LOGO)

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. For Annex IV products, Notified Body certificates issued in accordance with Annex IX and Annex X shall be referred in the manufacturers Declaration of Conformity. For non-Annex IV products, the manufacturer is not allowed to refer to the certificate in the Declaration of Conformity.

In case of incorrect reference to certification status or misleading use of certification documents or other breach of the applicable requirements for the maintenance and use of the certificates as submitted by DNV GL, DNV GL may decide corrective actions as well as suspension or withdrawal of certificate and publication of the transgression.

Manufacturer shall immediately implement such corrective actions.

DNV GL is not providing any certification marks for the MD.

13 PUBLISHING OF CERTIFICATES

By signing the PCA, the manufacturer agrees to let DNV GL publish on their external website basic information (e.g. certificate numbers, manufacturer name and product scope) about the issued certificates.