

PRESSURE EQUIPMENT

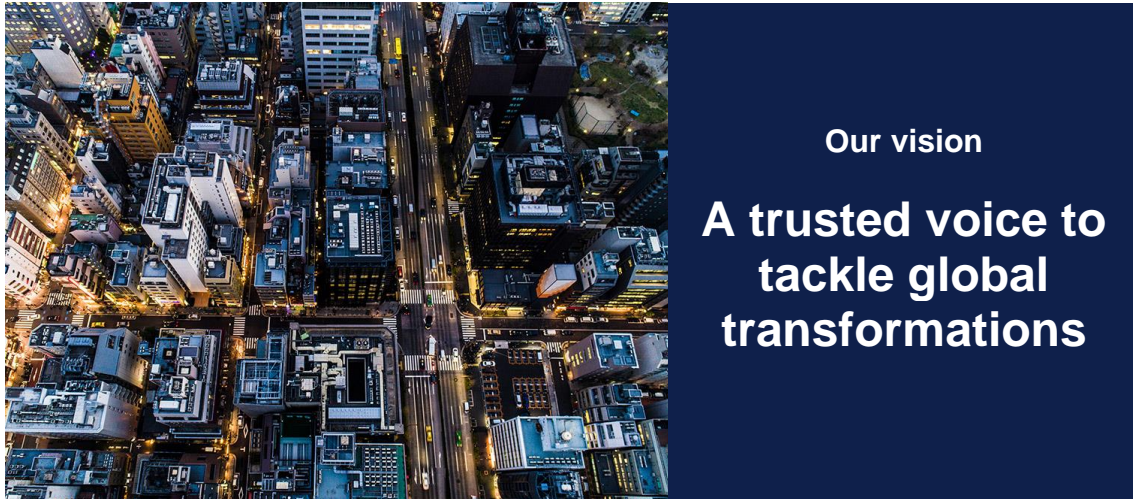
DNV certification requirements for pressure equipment

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1 SERVICE DESCRIPTION

This document describes the DNV conditions and certification processes for certification to the Pressure Equipment Directive 2014/68/EU (PED). The document defines Customer and DNV obligations additional to the Terms and Conditions in the Product Certification Agreement between the parties and in the Certificate.

Following the definitions in PED 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

DNV will perform this service as a Notified Body in conjunction with PED.
The DNV Notified Bodies operating under these Certification Rules are:

- DNV Business Assurance Italia S.r.l. appointed as the Legal Unit by the Italian “Ministero dello Sviluppo Economico” as the Notified Body 0496. The notification is based on accreditation from Accredia.
- DNV AS Norway appointed as the Legal Unit by the Norwegian “Direktoratet for samfunnsikkerhet og beredskap” as the Notified Body 0575. The notification is based on accreditation from Norsk Akkreditering.

The notifications concern the following PED scope:

- Module A2
- Module B - Production type
- Module B - Design type
- Module C2
- Module D1
- Module D
- Module E1
- Module E
- Module F
- Module G
- Module H1
- Module H
- PMA

The Annex I:3.1.2 permanent joining services are described in a separate document: Welding Certification Requirements.

In addition, DNV can offer the following voluntary assessments associated with PED (not covered by accreditation):

- Module A Statement
- Art.4.3 Statement
- Component's Statement
- Material Manufacturers Certificate (MMC)

In the following text DNV shall be understood as the Notified Bodies 0496 and 0575, and all DNV units qualified to provide the service. The final certification is done at the Notified Body uniquely.

It shall also be understood that all references to manufacturer in this document is equally applicable for authorized representatives.

3 GENERAL CONDITIONS

The DNV Product Certification Agreement (PCA) for PED states the general terms and conditions for PED projects. The requirements in the PED Certification Requirements (this document) are referred to in the PCA and constitutes an integral part of the PED contracts.

The following general conditions are always applicable for PED projects provided by DNV:

- The certification will state compliance of the product to the relevant parts of the PED. 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 PED, which is transferred to national legislation in all European Economic Area (EEA) member states
- If the requirements in PED do not provide sufficient guidance for evaluating the product the official PED Guidelines should be applied in first hand. If further clarification is needed DNV will use the recommendations from the PED Conformity Assessment Body Forum (CABF-R) which are commonly accepted by the Notified Bodies.
- DNV will not provide any consultancy services aiming to facilitate the certification.
- All product information needed for the DNV evaluation of the product is treated as confidential.

4 DNV CERTIFICATION PROCESS



DNV is one of the world's leading certification, assurance and risk management providers. Whether certifying a company's management system or products, providing training, or assessing supply chains, and digital assets, we enable customers and stakeholders to make critical decisions with confidence.

4.1 Application

Upon reception of a Request For Quotation (RFQ) sent by a manufacturer, DNV will draw up a Product Certification Agreement (PCA) for PED describing all activities involved in the certification process priced according to valid price list. The RFQ will be provided by DNV. The manufacturer must send all relevant information about the product and the system subject for certification in order to draw up a correct PCA. The PCA shall be signed by an authorized representative of the manufacturer and returned to DNV.

By completing and signing the PCA, 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.

4.2 Activities

DNV has the overall responsibility to carry out the Notified Body services in accordance with the regulation given by the notifying authorities and guidelines given by the national accreditation bodies. This also includes the work carried out by the Local DNV Units.

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

The manufacturer agrees to promptly supply to DNV, 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 technical file must in any case be made available for DNV.

For Module B-production type and Module G a design assessment precedes the site visit where a type test shall be witnessed (Module B – production type) or a product inspection is performed (Module G). In this case the design review shall be completed, and the design approved before the site visit.

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

For existing customers may DNV on certain conditions agree to perform site assessment activities without an assessor being present by using Information Communication Technology (ICT).

4.3 Issuing of certificate

When all assessment activities are completed, all records and correspondence, including results from the assessment activities and their main conclusions will be filed by the Notified Body.

The project is ready for Certificate issuance when the project file is found satisfactory by the Notified Body.

DNV will issue all formal documents and certificates according DNV's notification (see point 2 of this document). The validity of the certificate depends on the module:

Module	
A2, C2	No validity for unit verification When serial production 3 years or 5 years according to agreement with the manufacturer
B-production type, B-design type	10 years
H1 – design examination	10 years (0496), No validity (0575)
D, D1, E, E1, H, H1	3 years
F, G	No validity – Unit verification

The manufacturer shall keep the technical documentation for the pressure equipment or assembly that is in conformity with the Directive at the disposal of the national authorities for 10 years after the equipment has been placed on the market.

The technical documentation to be kept, including the certificates issued by the notified body and the EU declaration of conformity for each pressure equipment or each model as applicable, is the one indicated at Annex III of PED for the pertinent Module(s).

5 REFUSAL OF CERTIFICATION

Certification shall be refused if the product or the quality system is found not to comply with PED. DNV shall communicate refusal of certification to the applicant in writing. Information regarding the appeal procedures shall be given.

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

6 MAINTAINING THE CERTIFICATE

The manufacturer must at all times ensure that the requirements of the standards under the certification scope are complied with and undergo all DNV scheduled assessment activities and visits. Corrective actions to identified findings must be implemented within the set time limit.

The manufacturer shall authorize DNV 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 fees as stipulated in the PCA must be paid following the conditions for payment stated therein. The manufacturer is also obliged to keep a record of all complaints concerning the products under the certification scope. DNV will verify that the manufacturer has taken relevant corrective actions for these complaints in conjunction with the surveillance visits.

For some of the modules are in addition the following specific conditions applicable:

Module A2/C2:

The manufacturer shall inform DNV of the intended schedule of production when serial production is the case.

Module B – Design type:

The certificate is concerned with the design of the product only and the certified product(s) cannot be CE-marked based on this module only. The relevant documents in the manufacturers technical file are listed on the certificate.

Module B – Production type:

The certificate is concerned with the design and the testing of a prototype(s) only and the certified product(s) cannot be CE-marked based on this module only. The relevant documents in the manufacturers technical file are listed on the certificate.

Module D:

The manufacturer shall inform DNV of the intended schedule of production for pressure vessels and directly heated vessels with risk for over-heating in Category III and IV covered by the Certificate.

Module E:

The manufacturer shall inform DNV of the intended schedule of production for pressure vessels and directly heated vessels with risk for over-heating in Category III covered by the Certificate.

Module H:

The manufacturer shall inform DNV of the intended schedule of production for pressure vessels and directly heated vessels with risk for over-heating in Category III covered by the Certificate. In case of one-off production of fired or otherwise heated pressure equipment cat III with the risk of overheating, DNV shall perform or have performed the final assessment of each unit.

Module H1

Two kinds of valid certificates are necessary in order to put the CE mark on the product: the full quality assurance certificate and the design examination certificate. The full quality assurance certificate can only cover products under valid design examination certificates.

The manufacturer shall inform DNV of the intended schedule of production for pressure vessels and directly heated vessels with risk for over-heating in Category III and IV covered by the full quality assurance certificate.

Module H/H1, D/D1 and E/E1:

DNV must be informed of any sub-suppliers for main pressure retaining parts.

7 CHANGES IN STANDARDS

DNV 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.

The notified body shall keep itself apprised of any changes in the applicable standards which indicate that the certified product may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

8 CHANGES BY THE MANUFACTURER

Manufacturer must, when operating under a quality system-based module, 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 products being certified, to DNV before execution of such change. Failure to do so may result in a non-compliance being raised by DNV.

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

When applying inspection based modules (Module A2, C2, F, G) the DNV shall be made aware of any deviations being made during the process from any approved documents and applied standards.

9 SUSPENSION OR WITHDRAWAL OF THE CERTIFICATE

DNV may decide to suspend or withdraw the certificate and, in such cases, the manufacturer will be informed as soon as this is practicable.

NOTE: DNV must provide the possibility for appeals against its decisions.

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 pressure equipment according to the Directive
- The product is changed, and the manufacturer has not informed DNV about it
- The requirements for the quality system or the pressure equipment are no longer fulfilled
- The product is no longer covered by the Directive
- The pressure equipment 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 under consideration of the severity 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, dependent on the seriousness of the situation, DNV may decide a direct withdrawal of the certificate.

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

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

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 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 receives a written communication at least 60 days before the wished cancellation date authorizing DNV 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 certification activities.

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

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

The complaint or appeal may be registered on the DNV website alternately sent by letter or email to the nearest DNV office.

11.2 Initial handling and actions taken

Upon receipt of a complaint or an appeal DNV 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 complainant/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 CERTIFICATION MARK AND THE ACCREDITATION BODY MARK

The Manufacturer shall have the right to use the valid certificate and the DNV certification marks in standard size and design as provided by DNV for the purposes for which such certificates and certification marks are generally intended and used, including on letters, documents and other promotional material.

In case of incorrect reference to certification status or misleading use of certification documents or marks or other breach of the applicable requirements for the maintenance and use of the certificates and the certification mark as

submitted by DNV together with the certificate, DNV may decide corrective actions as well as suspension or withdrawal of certificate and publication of the transgression. Manufacturer shall immediately implement such corrective actions. The DNV certification mark is not to be mixed up with the CE-mark. The CE-marking shall be made by the manufacturer according to PED Article 18/19 and Annex I:3.3.

The manufacturer may not use the Certification Mark on the product, unless otherwise agreed in writing. The Certification Mark may be shown on Manufacturer's public relations material, provided it is directly related to the product which has been certified under this Agreement, and that the explanatory text is sufficiently precise. The Certification Mark must only be shown in standard size and design. Standard size and design may be obtained from DNV on request. The Certification Mark must never be shown as larger than Customer's own logo, but the Certification Mark must always be shown in its entirety.

The above described use of the Certification Mark is applicable for certification under the Quality Modules (Module D, D1, E, E1,H and H1). For Unit verification and certification based on monitoring (Module F, G, A2 and C2) the certification mark can only be used on technical documentation for the certified product. The Certification Mark to be used will be sent to the Manufacturer on demand. The layout of the Certification Mark is shown below:



For Notified Body 0496 the Accredia mark may be used by the Manufacturer following the "RG-09 Regulation for the use of Accredia mark". This document is found on the Accredia website www.accredia.it

For Notified Body 0575 the Norsk Akkreditering mark shall not be used by the Manufacturer; refer to document "dok00067". This document can be found on the NA website <https://www.akkrediter.no/>

13 PUBLISHING OF CERTIFICATES

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

14 INSURANCE

The DNV insurance is a comprehensive insurance program placed with market leading underwriters of no less than A rating.

DNVs insurance is purchased and expires on an annual basis.

DNV represents and warrants that it shall maintain in force the insurance cover at the same level as in the certificate on an annual basis for a period of 3 years after termination of the insurance, provided that insurance at this level is generally available in the market.