

DIRECTIVE 2014/68/EU (PED) – MODULE B3.1 EU-TYPE EXAMINATION – PRODUCTION TYPE

1. PURPOSE OF SERVICE

The PED Module B3.1 service proposed by Bureau Veritas is to assess the conformity of pressure equipment or assemblies to module B3.1 requirements, as defined in Annex III of Pressure Equipment Directive 2014/68/EU (PED) and national transposition.

The service shall be performed in compliance with the contract entered into between Bureau Veritas and the Applicant and/or the Bureau Veritas General Terms and Conditions of Service..

2. SCOPE OF APPLICATION

The service is performed by Bureau Veritas as a Notified Body, recognized by a European Member State, in compliance with statutory requirements and its own general procedures.

The conformity assessment procedure as per Module B3.1 is applicable to pressure equipment classified from category I to IV as defined in the Annex II of Pressure Equipment Directive 2014/68/EU (PED) and to assemblies classified up to category IV as defined in art. 14.6b of PED.

The assessment is carried out on a representative sample of the production envisaged, hereinafter called "type". The type may cover several versions of pressure equipment provided that the differences between versions do not affect the level of safety.

The applicant, applying for the assessment of the equipment or assembly, is the manufacturer who is responsible for design, manufacture and tests or its authorised representative. He must retain overall control and have the necessary competence to take the responsibility for the product.

3. APPLICABLE STANDARDS AND REGULATIONS

- European Directive 2014/68/EU (PED) and national transposition after July 19th, 2016
- The harmonized standards published in the Official Journal of the European Communities and national transpositions or equivalent standards ensuring the conformity with the essential safety requirements of the PED.
- European approvals for materials published in the Official Journal of the European Communities
- Official interpretation issued by European Commission (PED Guidelines) as published on the official website

4. PERFORMANCE OF SERVICE

The conformity assessment service as per Module B3.1, defined in PED Annex III and proposed by Bureau Veritas, consists in the examination of the design and construction of representative example (type) of pressure equipment and the performance during manufacture of appropriate tests or examinations, to ensure its conformity with the requirements of the PED which apply to it.

In particular Bureau Veritas will:

- Examine the technical documentation with respect to the design and manufacturing procedures (drawings, design calculations, test reports, list of relevant standards, etc)
- Check that relevant harmonised standards are applied or that the solutions adopted meet essential safety requirements.
- Assess the materials used where they are not in conformity with relevant harmonized standards or with European approval for pressure equipment materials.
- Check the certificates issued by the material manufacturer in accordance with section 4.3 of Annex I of PED with reference to the manufacturing of the assessed type.
- Check the qualification and, when applicable, the approval by a Notified Body or by a recognized third party of permanent joining procedures

- Check the qualification and, when applicable, the approval by a notified body or by a recognized third party of staff engaged in permanent joining and non-destructive tests
- Verify that the type has been manufactured in conformity with examined documentation and performs or have performed the appropriate examination and necessary test in order to establish that they meet essential safety requirements of PED.
- If relevant, witness tests and checks as required in harmonised standards or technical referential of the manufacturer
- Keep apprised of the acknowledged state of the art and may inform the manufacturer if any changes may put into question the conformity of the approved type with the applicable requirements of PED

5. CONDITIONS OF PERFORMANCE

The Applicant must:

- Lodge an official conformity assessment application stating:
 - His name and address
 - The relevant assessment module, description of equipment concerned, identification of type(s) and its represented family and relevant classification of risk category as per PED.
 - A written declaration to the effect that a similar application has not been lodged with another Notified Body.

The application must be lodged by the Manufacturer or by his authorized representative established within the European Community, using the model of Application Form provided by Bureau Veritas

- Provide Bureau Veritas with full technical documentation in duplicate concerning the equipment for assessment, as stipulated for module B3.1 (cf. PED Annex III), regarding design, manufacture and operation.
- In the case of the experimental design method, prepare a test programme as defined in the directive annex I, paragraph 2.2.4, has to be included.
- Place at the disposal of Bureau Veritas one type or more (should the test program so require)
- Provide Bureau Veritas inspector with any measures needed to perform the inspection on the type (e.g. preparation of the equipment, lifting means and easy access to all part to be inspected, good lighting system, supply of the fluids and accessories necessary for the tests).
- When requested by Bureau Veritas, provide all measuring equipment used during the fabrication, inspection and testing. The equipment shall be calibrated accordingly, and the evidence of the current calibration shall be provided to the PED inspector for verification. In case the applicant issues NCR relating to calibration, he shall inform Bureau Veritas and propose appropriate corrective actions.
- Inform Bureau Veritas of all modifications to the approved pressure equipment; these are subject to additional approval in the form of an addition to the original EU-Type examination – production type certificate.
- Allow the Bureau Veritas access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information.

The Bureau Veritas inspector(s) must be accompanied by a representative of the applicant during the inspection.

The realization of the inspections on the premises is possible only where the technical conditions laid down by the directive can be achieved and the technical manufacturing documentation is made available to the inspector.

The applicant is responsible for ensuring a safe working environment to the Bureau Veritas inspector(s), wherever the performance of work takes place. All appropriate measures must be taken, in accordance with applicable laws and regulation, international standards and state-of-the-art practices.

SCOPE OF SERVICE DESCRIPTION / INDUSTRY SERVICES

Evidences of satisfaction/performance of the above mentioned measures must be provided to the Bureau Veritas inspector(s) (if applicable) before the beginning of the inspection.

If Bureau Veritas Inspector evaluates that his health or safety is exposed to a serious, uncontrolled and imminent risk, he or she may postpone the inspection.

As requested in PED 2014/68/EU, the applicant shall:

- keep the technical documentation and the EU declaration of conformity for 10 years after pressure equipment or assemblies have been placed on the market.
- further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly with this Directive, in a language which can be easily understood by that authority

6. BUREAU VERITAS DELIVERABLES

The deliverable that may be expected from Bureau Veritas are:

- Upon completion of each visit, an inspection report is issued containing for instance:
 - details of service performed,
 - observations made,
- When the production type meets the relevant provisions of the Directive, an "EU-Type examination – production type certificate" is issued. It remains valid for 10 years and is renewable, unless any significant change occurs in the generally acknowledged state of the art

7. LIMITS OF THE PRESENT SERVICE

The assessment procedure to Module B3.1 doesn't allow to apply the CE mark on the equipment; the conformity assessment to PED shall be completed with another Module (C2, D, E or F) relevant to the manufacturing phase and chosen by the manufacturer in accordance with the classification of risk category of the equipment.

Moreover, the services described in the present document does not include in particular the following ones:

- Any service under the terms of another EC Directive applying to the relevant item,
- Qualification of permanent joining procedures and operators
- Approval, by Notified Body, of operating procedures and personnel for permanent joining.
- Qualification of Non-destructive tests personnel
- Approval, by Notified Body, of personnel for non-destructive tests
- Destructive and non-destructive tests.
- Material Manufacturer Quality System Assessment
- Material Certificates of specific product control (e.g. Certificate type 3.2 as per EN 10204).

8. OTHER SERVICES

Subject to an express agreement by the parties, the assessment as per Module B3.1 service may be supplemented, when appropriate and/or allowed by the Notification held by Bureau Veritas, by other services such as:

- Qualification of welding procedures and welding operator
- Approval as notified body, of operating procedures and personnel for permanent joining
- Approval as notified body, of personnel for non-destructive tests

9. COMPLAINTS AND APPEALS

Should the Applicant wish to appeal against or dispute any decision of Bureau Veritas, it should do so in accordance with the Bureau Veritas appeals procedure, available upon request.

Should a complaint arise about Bureau Veritas, such complaint shall in the first instance be made to the local Bureau Veritas office. **If the Applicant does not wish to complain directly to the local Bureau Veritas office, the complaint shall be sent in writing to Bureau Veritas Services,**

Le Triangle de l'Arche - 8 Cours du Triangle 92800 Puteaux FRANCE, attention to I&F TQR Direction.

10. CONFIDENTIALITY

The national competent authority may request from Bureau Veritas as a Notified Body information which Bureau Veritas and the Applicant may consider confidential.

The provision of such information to the national competent authority is a mandatory requirement for Bureau Veritas as a Notified Body and shall not be considered as a breach of confidentiality by Bureau Veritas.

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