

DIRECTIVE 2014/68/EU (PED) – MODULE C2 CONFORMITY TO TYPE

1. PURPOSE OF SERVICE

The PED Module C2 service proposed by Bureau Veritas is to assess the conformity of pressure equipment or assemblies to module C2 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 C2 applies to manufacture, final inspection and testing of pressure equipment and assemblies already positively assessed as per Module B3.1 and therefore having a valid EU-Type examination – production type certificate (Module B3.1) or EC Type examination (module B3.2) issued to the applicant by a PED Notified Body.

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.

The conformity assessment procedure as per Module C2 is applicable to pressure equipment classified up to category III as defined in the Annex II of Pressure Equipment Directive 2014/68/EU (PED) and to assemblies classified up to category III as defined in art. 14.6.b of PED.

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 C2, defined in PED Annex III and proposed by Bureau Veritas, consists in a monitoring service in the form of unexpected visits in order to check the conformity with the approved type described in the relevant EU-Type examination – production type and with relevant requirements of PED.

In particular Bureau Veritas will:

- Perform unexpected visits at the premises where final assessment is carried out, in order to establish that the manufacturer actually performs final assessment in accordance with section 3.2 of annex I of the PED
- Take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks and monitor all or part of the final assessment.

The acceptance sampling procedure (ref ISO 2859-1) to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits

The number of visits and their periodicity has to be defined in function of the results and findings of earlier unexpected visits (at least 2 visits are performed for a 12 month period).

5. CONDITIONS OF PERFORMANCE

The Applicant must:

- Lodge an official conformity assessment application stating:
 - Relevant assessment module (C2),
 - all applicable and relevant information on pressure equipment concerned (type, identification, classification of risk category as per PED)
 - Scope of application (estimated number of items of equipment and/or period during which the survey is to be carried out).
 - Relevant EU-Type examination – production type certificate and its annexes issued to the applicant by a notified body.

The application must be lodged by the Manufacturer, using the model of Application Form provided by Bureau Veritas

- Provide Bureau Veritas before the beginning of the inspection with:
 - Full technical documentation in duplicate concerning the equipment for assessment regarding manufacture, final assessment and testing and for check of the conformity with the approved type described in the relevant EU-Type examination – production type certificate.
 - All descriptions and explanations needed to clarify the drawings, diagrams and functioning of the pressure equipment,
- Submit to Bureau Veritas
 - Timetable for performance of final assessments to be monitored, enabling the inspector to carry out unexpected visits. Whereas the applicant stops its production, he has to send relevant official statement to Bureau Veritas in order to suspend scheduling of unexpected visits.
 - A complete annual list of equipment manufactured within the framework of the application and bearing the notified body number assigned to Bureau Veritas.
- Allow Bureau Veritas access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information.
- Provide the Bureau Veritas inspector with any measures needed to conduct the checks (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.

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

The realization of the final assessment 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.

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 by 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,
 - Review of solutions proposed by the manufacturer to correct any discrepancies and non-conformities observed
- When the conclusions of the verifications are satisfactory, a letter of authorization is issued in order to affix the Bureau Veritas Notified Body identification number on the equipment concerned and to draw up the declaration of conformity. The validity of this letter of authorization cannot exceed the duration of the contract with Bureau Veritas

For series production, the authorisation letter is maintained on condition that results of unexpected visits are satisfactory

7. LIMITS OF THE PRESENT SERVICE

This service described in this document does not include in particular:

- Any service under the terms of another EC Directive applying to the relevant item,
- Design conformity assessment,
- Particular Material Appraisal
- Qualification of permanent joining procedures and operators where appropriate,
- Approval, as Notified Body, of operating procedures and personnel for permanent joining.
- Qualification of Non-destructive tests personnel
- Approval, as 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 C2 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
- Any service relating to modification of type

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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