

Number: MS-0034720

Revision:

Effective date: Jun 15, 2021
Author: Katarzyna Cichon
Approver: Ewa Krajewska
Process Owner: Susanne Aretz

# **Certification conditions BS I**

**Legal Scope:** 

TÜV Rheinland Polska Sp.zo.o.

**Business Scope:** 

**I.01 Pressure Equipment** 

**Process Scope:** 

6.3 Service Delivery

NOTE: These testing and certification conditions will be effective upon notification and publication of the scope update in the NANDO list (http://ec.europa.eu/growth/tools-databases/nando/).

# 1. Objectives

The determination of rules, procedures and management for implementing product, process and service certification by TÜV Rheinland Polska Sp. z o.o. in Business Field I.01.

### 2. Terms and Abbreviations

Terms/Abbreviations	Description				
test objects	applicant's products, processes, services and management				
	systems				
applicant	interested organization or person (especially product				
	manufacturers); organization or person responsible to a				
	certification body for ensuring that certification requirements				
	are fulfilled. Whenever the term "applicant" is used in those				
	certification conditions, it applies to both the "applicant" and				
	the "client", unless otherwise specified.				
certification body	third-party conformity assessment body operating certification				
	schemes. In those certification conditions - TÜV Rheinland				
	Polska Sp. z o.o.				
certification program	Conformity assessment system related to specified objects of				
	conformity assessment, to which the same specified				
	requirements, specific rules and procedures apply				
test plan	individual steps of evaluation in related scope e.g.				
	inspection/audit plan				
expert	Qualified and authorized by Certification Body personnel				
	involved in certification procedure (eg. Inspector, auditor)				



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#### 3. Scope of Application

These certification conditions apply to the following conformity assessment bodies of TÜV Rheinland Polska Sp. z o.o. ul. Wolności 347, 41-800 Zabrze Business Field BF I.01

### Body:

- Notified Body for pressure equipment
- Notified Body for simple pressure vessels
- Notified Body for construction products
- Notified Body for transportable pressure equipment
- Certification Body for Welding Manufacturers
- Certification Body for Material Manufacturers
- Certification Body for qualification of welding personnel

(hereinafter referred to as "certification body").

These certification conditions are published on web page www.tuv.pl

The certification body offers interested companies, especially product manufacturers (hereinafter referred to as "applicants") the following services; testing, inspection, auditing, certification and, if required, surveillance and recertification of a test objects, with a statement about the conformity of the test objects with the underlying requirements.

The test objects can contain the applicant's products, processes, services and management systems.

The certification is based on the requirements set out in the applicable regulations, specifications and, in particular, in respective certification programs. Test objects are evaluated against the requirements covered by the scope of certification and other requirements specified in respective certification program.

The certification body works as an independent third party. It is recognized and authorized as such for these activities

Depending on the scope of activity the authorization is based on:

- an accreditation by the Polish Centre for Accreditation (PCA)
- a notification by an authority issuing a national authorization or
- another approval of the body.

These certification condition regulates:

- the execution of the conformity procedure
- the duties and responsibility of the certification body as well as
- the tasks, obligations and rights of the applicant.

The corresponding requirements are based on the requirements of the series of standards, EN ISO/IEC 17000 as well as on the certification program applicable to the respective test object.



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All the interrelationships, specific requirements and the rules and procedures for carrying out the conformity assessment are set out and made available to the public in a certification program. A certification program is developed, prepared and approved by competent persons, a group composed of representatives of different groups (e.g. manufacturers, consumers or authorities).

The certification body normally uses prepared certification programs which have been devised and adopted by independent commissions, expert bodies or trade associations and which have been recorded in regulations and standards (guidelines, laws, ordinances, technical rules, standards, specifications and accreditation criteria etc.). The certification body is therefore not the owner of the certification program but merely the user of the program.

A certification procedure comprises the following steps application review, evaluation, review, certification decision.

The application review step comprises in this procedure the review of all input information submitted by applicant to check if application is complete.

The evaluation step comprises in this procedure the planning and selection of the scope of testing, inspection, auditing or certification well as the determination of the results. The test results are summarized in a report.

In the review step the results are assessed. It is the basis for a certification decision and includes an assessment of all required information and results related to the evaluation. In case of any nonconformities or missing documents, process documentation goes back to step evaluation.

In the certification decision step the final decision is made. If the properties of the test object comply with the requirements the certificate (certificate of conformity) is issued.

Steps evaluation and review are carried out independently of each other and by different persons (4 eyes principle).



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### 4. Principles

### 4.1 Application review

The interested applicant makes an enquiry of the certification body about the certification procedure either by letter/e-mail/telephone or by completing and submitting respective template provided by the certification body.

The certification body requires the following details and information about the applicant:

- Applicant's name and address and contact name;
- Type of evaluation (first certification/monitoring/recertification/modification);
- Expected scope of application and scope of the certification;
  - description of the test object (product/process/service),
  - details of the requirements of the test object (standards, specifications),
- Details about the applicant's company;
  - locations,
  - personnel, equipment, processes (manufacturing processes), subcontractors,
  - details of respective certifications already held.

The certification body will rely on evaluation results related to certification completed prior to the application for certification, where it can take responsibility for the results and satisfies itself that the body that performed the evaluation fulfils the requirements contained in the certification scheme.

NOTE This can include work carried out under recognition agreements between certification bodies.

The certification body decides on the basis of the enquiry about certification submitted by the applicant whether a certification procedure in accordance with the certification program is in principle possible. The applicant is informed if a certification procedure cannot be carried out.

If a certification procedure can be carried out, the offer is prepared, setting out the individual services, prices and conditions based on the scope of the certification applied for and the fees charged and calculations. The offer is then sent to the applicant.

The following applicable documents are enclosed with the offer:

- these certification conditions;
- related detailed certification conditions respective to the scope of certification;
- contract template on which the applicant can apply for the certification procedure.

To officially apply for the certification the applicant signs the frame contract with certification body and accept by order signing the financial offer conditions. By placing the contract the applicant accepts as binding certification conditions of certification body. As of the date of signature of the new contract, all contracts signed so far shall cease to be valid.

Changes contract agreements may be made in writing only.

Any ambiguities on the part of the certification body and applicant must be clarified.

Any differences in the perceptions of the certification body and the applicant must be resolved.



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Review of application information is conducted to ensure that:

- the information about the applicant and test object is sufficient;
- any known difference in understanding between certification body and the applicant is resolved, including agreement regarding standards or other normative documents;
- the scope of certification is defined;
- the means are available to perform all conformity assessment activities;
- the certification body has competence and capability to perform the certification activity;
- certification condition of certification body are accepted.

#### 4.2 Evaluation

By way of preparation for the evaluation step the applicant has to provide the certification body in advance with specific documents, records and verifications specified in the related certification condition in explicit scope depending of the expected scope.

The documents are to be submitted to the certification body in Polish or in English. The documents can be submitted in another language only by prior agreement.

The certification body defines a generic plan applicable to all activities according to the scope of certification and based on the certification program.

The evaluation on the respective object is carried by authorized experts by certification body.

These experts perform checking the documents submitted as well as evaluation on site at the applicant's company.

The applicant is sent a test plan which notifies him/her of the procedure and scope of the evaluation. The evacuation covers the points specified in the certification program (respective regulations, standards or own certification program).

The evaluation is carried out by the experts in accordance with the test plan. Individual steps as part of the test can also be carried out on a subcontract basis by qualified external subcontractors (only by prior acceptance with applicant) – see also 4.9.5.

If inconsistencies between the real situation and the application were identified during the assessment, the body may make changes to the assessment plan, schedule additional time or, if justified, withdraw further assessment.

The expert will record under "Notes" any possibilities for improvement observed during the evaluation of the test object.

If specific requirements of the test object are not met, the experts will record this as nonconformity. Any nonconformity detected is to be rectified by the applicant in a reasonable time period by appropriate correction and corrective action. Evidence that the actions have been carried out is to be submitted to the experts.

Special additional evaluation can also be carried out by the expert in the case of serious/impermissible nonconformities (e.g. if the personnel do not have the required qualifications, lack of equipment, inadequate product design).

In this special evaluation the experts check whether the nonconformities have been effectively rectified by the correction actions taken.



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The experts set out the result of the evaluation (including any nonconformity found) in a written report which is delivered to the applicant.

#### 4.3 Review and certification decision

Provided no objections were raised by the expert during the evaluation and all the nonconformities detected have been rectified, the experts' report with the associated documents is verified by authorized reviewer at the certification body.

The reviewer assesses the report for conformity with the requirements (formal and technical review). If the requirements are met and if conformity is proved, the certificate or other relevant document is issued by authorized in certification body certifier and delivered to the applicant. If the requirements are not met, a certificate is not issued and the applicant is informed in writing by the certification body of the negative decision and of the reasons for the decision.

#### 4.4 Certificate, test mark

If applicable, at least the following information is shown on the certificate:

- Applicant's name and address
- Certificate number
- Scope of application/scope of the certification

(test object/certification program/product standard, certification stage, characteristic values and parameters if applicable)

- Reference to the evaluation on which certification is based
- Date of issue
- Period of validity of the certification
- Signature
- Name and address of the certification body
- any other information required by the certification scheme

The date of issue of the certificate not precede the date on which the certification decision was completed.

A certificate remains valid as long as the requirements and the conditions on which certification was based remain unaltered.

The certification body can also allot a test mark for certain test object in addition to the actual certificate. The scope of application and the standard on which certification is based are shown on the test mark as well as an individual identification number and the entry on the TÜV Rheinland website "Certipedia" (www.certipedia.com). A QR code can also be used as a link to this website. The validity of the test mark is linked to the validity of the certificate.



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#### 4.5 Surveillance

In the case of certain test objects (e.g. design type, operating management systems) the validity of the certification and compliance with the requirements of the certification are monitored at regular surveillance intervals by the certification body, according to the related certification program and respective certification conditions of Certification Body. Surveillance evaluation step is required in this process at specified intervals.

The certification body authorized experts to carry out the corresponding surveillance.

The surveillance evaluation is carried out in accordance with the procedure described in chapter 4.3, with special emphasis also placed on checking the effectiveness of measures taken to rectify previous nonconformities.

The approved certifier decides on the basis of the review result whether the certification is to be maintained, suspended or even revoked.

In cases where such action is justified, for example where complaints and appeals have been made, the certification body can also require that special evaluation be carried out.

## 4.6 Extension of the certification (recertification)

If the period of validity of the certificate is limited, the following procedural steps application review, evaluation, review, certification decision, surveillance (if applicable) must be repeated in order to make an appropriate extension to the validity of the certification after it has expired (chapter 4.1-4.6).

### 4.7 Changes in scope of certification

If the certification requirements change (e.g. because the certification program on which certification is based has been revised) the certification body will inform the applicant in due time about these changes as well as about any adjustment measures that need to be taken.

In case of any changes on the part of the applicant, the conditions described in clause 4.10.3 shall be applied.



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### 4.8 Withdrawing, restrictions, suspension, revocation

Where infringements of the certification program and of these certification conditions have been identified, the certification body can require the applicant to take appropriate corrective measures. In extreme cases the validity of a certification can be lapsed or suspended, restricted or revoked.

A certification is withdrawing when:

- the period of validity stated on the certificate has expired and has not been extended
- the contract for certification has been cancelled by the certification body or applicant after 3 months' notice of cancellation has been given.
- the applicant relinquishes the certificate
- the applicant becomes insolvent
- the regulations on which the certificate was based have changed.

A certificate can be restricted, suspended or revoked by the certification body if:

- nonconformities from the certification requirements occur following the issue of the certificate,
- the applicant refuses to allow surveillance or does not enable it to take place,
- and does not allow the certification body to carry out surveillance despite a written request,
- the certificate (or test mark) is used in any manner that might mislead,
- or impermissible advertising is carried out using the certificate (or test mark),
- facts have come to light that could not be detected at the time of the issue of the certificate,
- corrective measures required to correct nonconformities were not taken in a reasonable or specified time limit,
- fees due to the certification body have not been paid after a reminder in the time limit set.

When test object no longer fulfils certification requirements, before declaring a certificate restricted, suspended or invalidated the certification body will give the applicant the opportunity of putting his/her side of the case unless such a hearing cannot be justified because of the urgency of the measures to be taken.

The certification body can ask the applicant to return the certificate when revoking the certification.

The certification body will publish the lapsing or revocation of the certification as appropriate and is entitled to inform certain bodies such as the accreditation body or the authorities/surveillance authorities issuing the authorization about the issue, lapsing or revocation of certificates.

In case restriction of certification, the Certification Body informs the Client in writing and makes necessary changes as to the certification status in certification documents and public information.

The certification body shall not be liable for any damage the applicant may suffer because a certificate has not been granted or because a certificate has been lapsed or revoked.



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### 4.9 Duties and responsibility of the certification body

## 4.9.1 Obligation of the certification body

The certification body undertakes to meet all the requirements made of it based on:

- the certification program on which certification was based
- the corresponding accreditation requirements
- the legal/official requirements

(especially in the case of a notification by an authority issuing an authorization).

The certification body will ensure that the principles such as impartiality and independence, competence, responsibility, openness and confidentiality will be maintained and that complaints and appeals will be dealt with independently, impartially and without bias. The certification body is responsible for all its certification activities.

The certification body works as an independent third party, free from any pressure and influence and with no conflicts of interest so that reliance can be placed on the statements of conformity on the certificates it issues.

The certification body is a part of legal entity TÜV Rheinland Polska Sp. z o.o. and is a member of the TÜV Rheinland Group:

TÜV Rheinland Polska Sp. z o.o. ul. Wolności 347, 41-800 Zabrze Business Field BF I.01 "Pressure Equipment and Plant Technology"

TÜV Rheinland Polska Sp. z o.o. has been registered under the number KRS: 0000081930.

#### 4.9.2 Impartiality

The certification body ensures that it will offer its services to all interested applicants on the same equitable terms and will carry out these services impartially, objectively and in a non-discriminatory manner.

The persons involved in a certification procedure and experts and subcontractors are not subject to any conflicts of interest in their work. They do not participate in the planning and development, manufacture, marketing, operation and maintenance of the test items falling within the scope of application of the certification. Nor do they carry out any advisory activities with the applicants concerned. The remuneration of the personnel is not based on the number of inspections carried out or certifications issued out or on their outcomes.

Moreover, the impartiality of the certification body is monitored by a impartiality committee (as a "means of ensuring impartiality"). Those committee is composed of representatives of different interest groups and stakeholders.



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The certification body is not designer, manufacturer, installer, implementer, operator, distributer or maintainer of the certified test object; provider or maintainer of the certified object and not offer or provide consultancy to its clients especially not offer or provide management system consultancy or internal auditing to its clients where the certification scheme requires the evaluation of the client's management system.

The certification body ensure that activities of separate legal entities, with which the certification body or the legal entity of which it forms a part has relationships, do not compromise the impartiality of its certification activities.

The certification body ensure that all personnel of certification body or committees who could influence the certification activities act impartially.

#### 4.9.3 Competence

Personnel engaged in a certification procedure are qualified, competent and authorized by the certification body to work as application reviewers, inspectors (auditors), reviewers and certifiers. The personnel are employed by TÜV Rheinland or are contractually bound to the certification body. The performance of the personnel is regularly monitored by the certification body.

## 4.9.4 Equipment

The testing equipment and facilities used in a certification procedure, especially in the evaluation step are suitable for the required tests. The testing equipment has been calibrated and the testing and evaluation software has been validated.

### 4.9.5 Subcontracting

Individual partial tests, especially as part of the evaluation step, can be also be subcontracted or outsourced by the certification body to competent and qualified external companies in scope od laboratory testing and other parts of the assessment tasks, e.g. carrying out inspections or audits.

External approved laboratories or, as appropriate, of accredited laboratories. There is also the possibility to witness the test held by client laboratory. In any case, the relevant requirements of EN ISO 17025 shall be maintained according to the instructions of MS-0034501.

Certification Body maintains a list of qualified subcontractors and keep documents from the assessment of subcontractors' competence and its works.

The results of such subcontracted/outsourced tests are incorporated in the report as well as in the review and decision on certification. The certification body retains responsibility for subcontracted/outsourced activities, i.e. the evaluation of the execution of the subcontracted partial tests as well as the assessment of the corresponding test results are carried out in all cases by the experts of the certification body themselves.

If the certification body intends to include external bodies in subcontracting a certification procedure, it has to inform the applicant accordingly and obtain his/her permission for this.



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### 4.9.6 Confidentiality

The certification body undertakes to treat in confidence all the information made available to it about the test item to be certified or about the applicant and to use this information only for the agreed purpose. Information about the applicant obtained from sources other than the applicant (e.g. from the complainant or from regulators) are treated as confidential. No information obtained from certification activities will be made available to third parties without the express written consent of the applicant. This commitment to treat information in confidence applies to all personnel at the certification body as well as to associated committees and external (e.g. subcontracted) bodies). The applicant will be informed if the law requires information to be disclosed to third parties (e.g. to official authorities) and he/she will be informed of the extent of the information disclosed.

The applicant can release the certification body on certain grounds from its obligation to maintain secrecy.

#### 4.9.7 Openness / information

The certification body will disclose all information about the certification program and certification procedure, the costs to the applicant, the conditions of use for the certification as well as the procedure for handling complaints and appeals.

Most of this information is provided in these certification conditions, which form part of the contract between applicant and Certification Body. General calculation rules on the fees charged to applicants are available on request. Calculation is always based on application data's.

### 4.9.8 Records / register of the test items certified

The following records in particular serve to document a certification procedure in a comprehensible manner test plan, report (including nonconformity report, corrective measures), certificate.

The originals of these documents are sent to the applicant. A second copy is filed and archived at the certification body electronically. The documents are archived for at least 10 years (or for at least 2 certification cycles in the case of the surveillance and extension of the certification). Additional legal requirements remain unaffected.

The certification body maintains a register of all valid certifications (showing the applicant's name, test object/product, certification program/regulations on which certification is based and scope of application of the certification).

The certification body maintain information on certified products which contains at least the following: identification of the object; the standard(s) and other normative document(s) to which conformity has been certified; identification of the applicant. The list of certified objects is available upon request. As a minimum, the certification body shall provide information, upon request, about the validity of a given certification. Depending on the certification program valid certifications (e.g. on design types, management systems) will be published on the TÜV Rheinland website "Certipedia" (www.certipedia.com).



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Appeals against test results or decisions on certification or complaints about the certification body can be submitted to the certification body by the applicant himself/herself or by other interested groups.

### 4.9.9 Change in the certification requirements

The certification body will inform the applicant of all relevant changes (affecting the certificate) in terms of the requirements of the test item to be certified, especially of changes to the certification program (or product standards) on which certification is based. The certification body will also inform the applicant about all adaptation measures to be taken (Chapter 4.8).

After changes have been made to the certification requirements the certification body will check within a specified period the adaptations that have become necessary at the applicant's company.

#### 4.9.10 Complaints/appeals

The process of complains/appeals and defined responsibilities for undertaking this process are available on www.tuv.pl

Appeals against the decision of the certification body and complaints about the certification body should be addressed to the certification body in the first instance. Appeals and complaints that have not been, or cannot be, resolved by the certification body can be addressed to the scheme owner.

### 4.9.11 Responsibility/liability of the certification body

The certification body is legally responsible for the correct execution of the evaluation, for the decision on certification and for the statement of conformity on the certificate.

Any liability by the certification body to the applicant or third party exists only to the extent prescribed by law for willful intent or gross negligence. All further claims shall be excluded.

In particular, the certification body will not be liable for any damage the client may suffer because a certificate cannot be issued owing to an unfavorable test result.

## 4.9.12 Fraudulent claim of certification

The Applicant may not declare certification before issuing the certificate.

False declaration of certification may result in the consequences specified below:

- Certification body shall be entitled to terminate the contract without a notice
- Client shall be obliged to pay contractual penalty amounted at 10,000.00 PLN

Furthermore, Certification Body can provide information to the market and external organs especially when the safety requirements are not fulfilled and test object endangers the life or health.



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### 4.9.13 Acceptance of conformity assessment results

In some cases, applicant might have obtained the results of determination activities, such as testing, inspection or auditing, prior to making an application for certification. In such a situation, the conformity assessment result may be from a source not within the contractual control of the certification body. Such results can be considered in the certification process only in case below conditions are fulfilled:

- for testing, it should meet the applicable requirements of ISO/IEC 17025;
- for inspection, it should meet the applicable requirements of ISO/IEC 17020;
- for management system auditing, it should meet the applicable requirements of ISO/IEC 17021.

Furthermore, certification body will accept certifications already held and issued by other Notified Bodies or Certification Bodies with existing accreditation in specified scope. Applicant should inform about certification already held, it could have the impact on the calculation of time. The certification body reserves the right to verify the authenticity of the copy of certificate and related documents.

Detailed conditions of acceptance of conformity assessment results are defined in certification condition in specified scope.

#### 4.9.14 Sampling

Where applicable, the certification body defines in specified certification conditions the extent to which sampling of the test object to be certified is required, and on what basis such sampling should be undertaken both at the evaluation and surveillance stages and who is permitted to undertake it.

### 4.10 Rights and obligations of the applicant

### 4.10.1 Obligations of the applicant

The applicant will ensure and undertake that all the requirements made of his/her company and the test object by the certification program and by these certification conditions are satisfied and will continue to be satisfied in the future as well. The applicant shall inform the body of any relevant aspects relating to the company or product (e.g. shift work) that may affect the planning and conduct of the assessment. The applicant is obligated to fulfils always the certification requirements, including implementing appropriate changes when they are communicated by the certification body and if the certification applies to ongoing production, the certified test object continues to fulfil the product requirements.

#### 4.10.2 Access to the applicant

The applicant has an obligation to cooperate. The applicant must provide the certification body with all the required information, data and documents relating to the application or the evaluation.



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In order to enable the experts from the certification body to carry out the scheduled evaluation and surveillance, the applicant shall grant them access to all relevant areas in the company (such as working and storage areas, including distribution warehouses) and to the test object (such as documentation, records, personnel, premises, production facilities, test facilities, equipment, products, client's subcontractors and complaints).

The applicant has also to provide access to his/her production facilities as well as to data and information to auditors of the certification body or the authorities issuing authorizations (e.g. PCA), for example, in the case of a witness audit.

The applicant (manufacturer) is obliged to calibrate the equipment used for inspection purposes in accordance with the manufacturer's recommendations and to check it before use. The applicant shall make available valid calibration certificates, verification documents and comply with the measurement consistency requirements. The expert (inspector) shall verify the validity of the certificates and check the equipment. If a defect in the equipment is found by the applicant before the inspection, the applicant should notify TÜV Rheinland Polska Sp. z o.o. of the defect and take corrective action. In the event of finding a non-conformity with the requirements of measurement consistency, the expert is obliged to terminate the inspection.

## 4.10.3 Information about changes

The applicant must notify the certification body immediately in writing of all changes affecting certification, such as changes to the organization, the procedures and processes e.g. the legal, commercial, organizational status or ownership, organization and management (e.g. key managerial, decision-making or technical staff, modifications to the product or the production method, contact address and production sites, major changes to the quality management system).

The certification body will inform the applicant about the measures to be taken to deal with these changes, check and verify the measures taken by the applicant. The following procedural steps application review, evaluation, review, certification decision, surveillance if applicable may have to be repeated (chapter 4.1 - 4.6).

## 4.10.4 Use of the certificate / test mark

The certificate certifies that the test object conforms to the prescribed requirements of the certification program. The declarations on the certificate relate solely to the test object inspected.

During the period of validity of the certificate the applicant is entitled to:

- use the certification (with the certificate and, if applicable the test mark) for advertising purposes in printed matter (such as brochures, leaflets and business documents)
- to depict the certificate (and, if applicable the test mark) in an unaltered form for advertising purposes

The design (composition, shape, color and typography) of the test mark must not be altered. It is not permitted to remove parts of the test mark.

The applicant must not distribute or publish test reports and certificates in an abridged form. Extracts of these documents may not be published without the prior consent of the certification body.



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The test mark must not be used in conjunction with or directly connected to other logos and marks. A sufficient gap should be left when placing the test mark next to other marks.

The applicant must not use the certificate (and, if applicable the test mark) in a misleading way but must use it solely for the designated scope of application. The certificate must not be used in a way that would bring the certification body into disrepute. The conditions of use for the test mark if allotted are set out in respective attachment.

After the suspension or revocation of the certification the applicant must cease to use any advertising that refers to the certification in any way. The applicant has to return all certification documents requested by the certification body after the revocation of the certification.

If the applicant provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in related certification program. The applicant in making reference to its test object certification in communication media such as documents, brochures or advertising, is obligated to complies with the requirements of the those certification conditions.

#### 4.10.5 Complaints

The applicant must record and archive all complaints and incidents affecting the scope of application of the certification. The applicant must provide these documents to the certification body and inform it about the measures he/she have taken to deal with the complaints when requested to do by the certification body.

### 4.10.6 Responsibility / liability of the applicant

The applicant is responsible for meeting all the requirements of the test object made by the certification program. The completion of certification by the certification body does not exempt the applicant from his/her statutory product liability obligation.

#### 4.11 Effective date and modification of those certification conditions

If individual provisions of these certification conditions become ineffective, the validity of any other provisions is not affected thereby. The certification body and the applicant shall replace the provisions recognized as ineffective by effective provisions which most closely approximate to the intended provision.

Polish law solely shall be applicable to the legal relationship existing between the applicant and the certification body.

These certification conditions came into force on 2018-07-06. All previous regulations became inoperative on the aforementioned date.

The certification conditions apply to all certificates issued during the period of validity. Future changes to these certification conditions can affect existing certifications. The applicant will be informed about this in writing by the certification body.



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Those certification conditions are published on Certification Body website. Those certification conditions are an integral part of agreement between Certification Body and Applicant.

### 4.12 Area of activity

Certification Body provides services in Poland and abroad. Services of Certification Body can be offered by local entities which are part of TUV Rheinland Group, but still the certification activities will be performed by Certification Body Personnel. In this special case, Certification Body in relations with Applicants could be represented by the mentioned local entity.

### 5. Roles & Responsibilities

Process Roles	Responsibilities					
Head of respective Certification Body/ Deputy	<ul> <li>Maintenance and publication of those certification conditions;</li> <li>Overall coordination including coordination with the top management;</li> <li>Development and maintenance of certification methods;</li> <li>Quality assurances;</li> <li>Personnel approval;</li> <li>Maintaining the notification (if applicable);</li> <li>Suitability of the certification method applied;</li> <li>Assurance procedures carried out by qualified personnel and in accordance with the regulations and the state of the art;</li> <li>Work equipment and installations deployed;</li> <li>Internal and external communication of required information;</li> <li>Application and implementation of the QM system;</li> <li>Cooperation with the notifying authority and other bodies according to the directives (if applicable);</li> <li>Reporting obligations to the notifying authority with regard to issuing, refusing, restricting, suspending and withdrawing certificates; and of all circumstances affecting notification (if applicable);</li> <li>Information (on request) to the competent authorities regarding conformity assessment activities, other activities, subcontracts (if applicable);</li> <li>Information to other notified bodies about negative and (on request) positive results of conformity assessments (if applicable);</li> <li>Maintenance of list of certified test objects;</li> <li>Provide information, upon request, about the validity of a given certification.</li> <li>The performance of individual tasks may be delegated by the heads to other certification body personnel. However, the</li> </ul>					



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responsibility for these delegated tasks remains with the
respective head of Certification Body.

#### 6. **Specifications**

N/A

#### 7. **Attachments**

N/A

#### 8. **Related Documents**

N/A

#### 9. **External Reference Documents**

ISO/IEC 17000 Conformity assessment -- Vocabulary and general principles

EN ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

EN ISO/IEC 17021-1 Conformity assessment - Requirements for bodies providing audit and certification of management systems

EN ISO/IEC 17024 Conformity assessment - General requirements for bodies operating certification of persons

EN ISO/IEC 17025 General requirements for the competence of testing and calibration *laboratories* 

EN ISO/IEC 17065 Conformity assessment - Requirements for bodies certifying products, processes and services



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Process Owner: Petr Lahner

# **Certification conditions TPED**

**Legal Scope:** 

TÜV Rheinland Polska Sp.zo.o.

**Business Scope:** 

I.01 Pressure Equipment and Plant Technology

**Process Scope:** 

6.3 Service Delivery

These detailed certification conditions are an integral part of the Certification Conditions BS I (MS-0034720). The certification conditions shall be read together.

NOTE: These testing and certification conditions will be effective upon notification and publication of the scope update in the NANDO list (http://ec.europa.eu/growth/tools-databases/nando/).

### 1. Objectives

The determination of a uniform detailed rules of conduct in carrying out the evaluation of transportable pressure equipment by TÜV Rheinland Polska Sp. z o.o. Notified Body 2627 for Transportable Pressure Equipment according to Directive 2010/35/EU.

These certification conditions are an integral part of the contract.

## 2. Terms and Abbreviations

Terms/Abbreviations	Description			
Test object	Transportable pressure equipment			
Applicant	Interested economic player involved in the manufacture of transportable pressure equipment			
Certification Body	TÜV Rheinland Polska Sp. z o.o. Notified Body for transportable pressure equipment 2627, Xa Body Inspection Body accredited under EN ISO/IEC 17020.			
Certification Program	Directive 2010/35/EU "TPED"			
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)			
RID	International Carriage of Dangerous Good by Rail (RID)			
Technical standards	Standards mentioned in ADR/RID			



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	a) Test plan - the purpose of an test plan is to record all
Test plan	actions which have to be proceed during the type approval
	and reassessment of conformity, test plan is prepared by
	Inspection Body
	b) Inspection plan – the purpose of an audit inspection is to
	record all actions which have to be proceed during the
	assessment; supervision of manufacture, initial inspection,
	reassessment of conformity, periodic inspection,
	intermediate inspection and exceptional checks, inspection
	plan is prepared by Inspection Body
	b) Audit plan – the purpose of an audit plan is to record all
	actions which have to be proceed during the surveillance of
	In-house inspection bodies audit plan is prepared by
	Inspection Body

#### 3. **Scope of Application**

These certification conditions apply to the following body

Notified Body for transportable pressure equipment 2627 TÜV Rheinland Polska Sp. z o.o. (hereinafter referred to as "Inspection Body" or "Notified Body").

Inspection Body offers interested economic players involved in the manufacture of transportable pressure equipment and making it available on the market of the European Union (hereinafter referred to as "applicants") the following services in accordance with the European Transportable Pressure Equipment Directive 2010/35/EU (TPED) in conjunction with the selected code of practice:

Conformity assessment of transportable pressure equipment:

- Conformity assessment:
  - Type approval assessment
  - Supervision of manufacture
  - Initial inspection
- Reassessment of conformity
- Periodic inspection, intermediate inspection and exceptional checks
- Certification and surveillance of In-house inspection bodies

The inspection body has been notified to the European Commission under the identification number 2627. The scope of the performed conformity assessment is accredited by Polish Accreditation Centre. Accreditation number AK 025.

The following rules and regulations are applicable:

- Directive 2010/35/EU (implemented in Poland by the Regulation of the Ministry of Ministry of Transport, Construction and Maritime Economy of 13 April 2012 on transportable pressure equipment)
- Relevant requirements of ADR/RID
- Requirement of applicable technical standard

Conformity assessments and inspections must be carried out by a Notified Body in accordance



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with the requirements in these regulations.

If the corresponding certificates of conformity and inspection reports of the notified body for the above-mentioned procedures required in each case are available, the manufacturer will issue the EU declaration of conformity and provide each piece of pressure equipment with the Pi mark as well as with the registered identification number of the notified body. This enables the transportable pressure equipment to be made available on the European market.

The "Certification program for transportable pressure equipment" is regulated by law and it is set out by the above-mentioned rules and regulations.

These documents have been prepared and passed by the European Parliament and the legislators of the individual states and, in the case of the technical standards, by the European Committee for Standards (CEN) which works under the mandate of the European Commission.

The certification body is therefore not the owner of the certification program for transportable pressure equipment but merely the user of this program.

## 4. Principles

#### 4.1 Application Review

Applicant may apply to Inspection Body by filing an application (T10 MS-0034793) or in equivalent way.

The applicant shall submit documentation equivocally identifying the test object indicated in the application.

In order to make a calculation, it is required to present at least information regarding test object.

The following details and information about the applicant are required:

- Company name, address, contact details, contact partner, number of employees if applicable
- Type of test object (procedure, procedure combination)
- Other data required by respective procedure see point 1.8.7 ADR/RID (if applicable)

Fees for the activities associated with the certification process are calculated according to the real allocation of time necessary for performing certification. The fees are determined on the basis of guidelines for estimation of expenditure adopted in the Inspection Body.

All information about services according to 2010/35/EU are available at the Inspection Body's web page including those certification conditions with related templates of application acc. to 2010/35/EU.

The precondition for commencing cooperation with the Notified Body is concluding a contract for conformity assessment according to 2010/35/EU including those certification conditions. The contract for conformity assessment according to 20140/35/EU remains valid for every subsequent application for conformity assessment.

The manufacturer may not apply for the conformity assessment to another notified body. Signing the contract shall be read as written declaration that the same application has not been lodged with any other notified body.



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Prior to the evaluation, the conditions of execution are agreed with the applicant and the completeness of the application is reviewed to ensure that the information provided is sufficient for the scope of certification and that the Notified Body has the necessary competencies and means to carry out the evaluation.

#### 4.2 Evaluation

Requirements for planning:

The date of evaluation is agreed with the applicant and the scope of the evaluation is presented in

- a) test/inspection plan for conformity assessment/inspection of transportable pressure equipment,
- b) audit plan for certification/surveillance of In-house inspection bodies
- 4.2.1 Requirements for technical documentation

The scope of the required documentation is presented in the point 1.8.7.7 of ADR lub RID.

The inspection body commissions authorised experts to carry out the corresponding steps.

The expert carries out the inspections/audits in accordance with the released plan. The results of the evaluation (inspection/audit) are summarised in a report.

4.3 Review and certification decision

No additional remarks acc. Certification conditions BS I (MS-0034720).

4.4 Certificate, test mark

If procedures are applied under which the Pi mark is affixed by the applicant, then the applicant is entitled to affix the Notified Body's identification number in combination with the Pi mark to his products. The identification number of TÜV Rheinland Polska Sp. zo.o. is 2627. A prerequisite is, however, that the successful certification according to the specified procedures within the scope of the TPED Directive has been accomplished.

The certificates/reports certify that the transportable pressure equipment conforms with the prescribed requirements.

The authorization to use the Notified Body's identification number applies only to the applicant and to its production facilities as well as to the products listed in the Certificate/document.

Certificates/documents validity:

- Type approval assessment, the certificate is valid no longer than 10 years,
- Supervision of manufacture, the certificate is valid for 1 year
- Initial inspection, the certificate is valid for an indefinite period, required to meet the dates of periodic and intermediate inspections and continuous compliance of respective requirements
- Reassessment of conformity, the certificate is valid for an indefinite period, required to meet the dates of periodic and intermediate inspections and continuous compliance of respective requirements
- Periodic inspection, intermediate inspection and exceptional checks:



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Equipment	Receptacles	Tanks 1	Tanks 2	Tanks 1	Tanks 2
		All class	All class	Class 2	Class 2
		Fixed tanks (tanks- vehicles), demountable tanks, battery- vehicles	Tank-containers, tank swap bodies, MEGC	Fixed tanks (tanks- vehicles), demountable tanks, battery-vehicles Class 2	Tank-containers, tank swap bodies, MEGC Class 2
ADR/RID	6.2	6.8.2.4.2	6.8.2.4.2	6.8.3.4.6	6.8.3.4.6
Periodic inspection	5 years	6 years	5 years	6 years	8 years
Intermediate inspection	2,5 years	3 years	2,5 years	On demand < 6 years	On demand < 8 years
Exceptional checks	If applicable	If applicable	If applicable	If applicable	If applicable

Certification/Surveillance of In-house inspection bodies, the certificate is valid for 3 year, required to meet surveillance audits every six months and continuous compliance of respective requirements.

#### 4.5 Surveillance

The surveillance process is applicable for supervision of manufacture, periodic inspection and surveillance of the applicant's in-house inspection service The results of the visits are reviewed and the decision of maintaining, suspending or withdrawing the certification is issued. In case of negative results depending on the seriousness of the identified irregularities the Notified Body may:

- suspend or withdraw certification,
- limit the scope of certification,
- carry out follow-up audits/special audit (if applicable).
- 4.8 Withdrawing, restrictions, suspension, revocation

Notified Body inform the notifying authorities of the positive or negative results of the assessments, periodically or upon request, make available to the notifying authorities the list of processes include negative decisions, a suspension or limitation decisions.

The Notified Body informs the other notified bodies about the processes include negative decisions, a suspension or limitation decisions. On request, information about issued certificates /reports.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the certificates/reports. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the certificates, reports, as well as the technical file including the documentation submitted by the manufacturer, until required retention period.

- 4.9 Obligations and responsibility of the certification body
- 4.9.1 Obligation of the certification body



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The Notified Body reserves the right to present the list of certified/inspected products on demand at the Body's premises.

The Notification Body is obliged to inform the notifying authority about:

- rejection, restriction or withdrawal of certificates,
- all circumstances, which may have negative influence on the notification process scope and conditions,
- every case of request for information received from the market supervisory activities regarding tasks associated with conformity assessment.
- on request, about activities undertaken in relation to conformity assessment that are subject to notification and about other executed tasks including cross-border activity and subcontracting.

The Body shall inform the Applicant or their representative upon every request about the requirements of Directive 2010/35/EU.

The Body shall carry out its duties taking into account the size, sector and structure of the involved businesses, the degree of the advancement of technology used in production and mass or serial character of the manufacturing process. However, the degree of rigor and the level of protection required for product conformity with the regulations of Directive 2010/35/EU shall be observed.

Applicant will be informed in case of new revision of those certification conditions not later than prior to accepting a new order. Every new edition of the Certification Conditions is published at the Inspection Body website.

#### 4.9.5 Subcontracting

The Notified Body may hire qualified subcontractors within the scope of performing laboratory tests with the Applicant's permission.

The Notified Body shall ensure that, in the above mentioned case, the applicable requirements of EN ISO/IEC 17025 (accreditation of required test methods).

The policy of the Notified Body relying on tests performed in production plants or external laboratories obliges the Notified Body to ensure information confidentiality and protect the Applicant's ownership rights in the course of the tests' execution.

If the conformity assessment requires the presence of the Notified Body in the course of the tests and the tests are being carried out in production plants using the applicant's laboratory equipment or external laboratory equipment and personnel, the Inspection Body is always present and supervises the execution of such tests.

Upon request, the Notified Body will provide the relevant notifying authority with the subcontractor competency assessment documents and work.

#### 4.10 Rights and obligations of the applicant

#### 4.10.1 Obligations of the applicant

In the event of planning the transfer of a production plant or other changes f.e change of the owner, takeover by another entity, applicant is obliged to inform Inspection Body not later than



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within 3 months (this refers in particular to the assessment procedures supervision of manufacture and certification and surveillance of In-house inspection bodies).

Prior to the commencement of the inspection at the pressure equipment site, expert shall be informed by the company's representative about the hazards that may occur, the applied collective and individual protection measures and their use, the manner of signalization between people working inside the equipment and the people who are assisting them outside the equipment, actions to be taken in the event of dealing with a threat.

4.10.2 Use of the certificate / test mark

In case the Certificate expires, or if it is declared invalid, the applicant loses the right to continue to affix the mark on the products indicated in the Certificate.

#### 5. **Roles & Responsibilities**

No additional remarks acc. Certification conditions BS I (MS-0034720).

#### 6. **Specifications**

N/A

#### 7. **Attachments**

N/A

#### 8. **Related Documents**

MS-0034720 - Certification conditions BS I



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#### 9. **External Reference Documents**

Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC

Directive 2008/68/EC of the European Parliament and of the Council off 24 September 2008 On The Inland Transport Of Dangerous Goods

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)

Convention concerning International Carriage by Rail (COTIF). Appendix C – Regulations concerning the International Carriage of Dangerous. Goods by Rail (RID)

EN ISO/IEC 17020 - Conformity assessment — Requirements for the operation of various types of bodies performing inspection

EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

Act of 19 August 2011 on the transport of dangerous goods

Regulation of the Minister of Transport, Construction and Maritime Economy of 13 April 2012 on transportable pressure equipment

Regulation of the Minister of Transport, Construction and Maritime Economy of 9 February 2012 on the method of determining fees for activities related to conformity assessment and testing of transportable pressure equipment and verification of their compliance with technical requirements.

Act of 13 April 2016. about conformity assessment and market surveillance systems

DAK-07 Accreditation of inspection bodies

DA-11 Accreditation of conformity assessment bodies for notification purposes

DA-06 Ensuring measurement consistency policy

DA-07 Policy concerning cross frontier accreditation