

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 evaluation 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, distributor 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 of 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 fulfil 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 comply with the requirements of 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 style="list-style-type: none"> ▪ Maintenance and publication of those certification conditions; ▪ Overall coordination including coordination with the top management; ▪ Development and maintenance of certification methods; ▪ Quality assurances; ▪ Personnel approval; ▪ Maintaining the notification (if applicable); ▪ Suitability of the certification method applied; ▪ Assurance procedures carried out by qualified personnel and in accordance with the regulations and the state of the art; ▪ Work equipment and installations deployed; ▪ Internal and external communication of required information; ▪ Application and implementation of the QM system; ▪ Cooperation with the notifying authority and other bodies according to the directives (if applicable); ▪ Reporting obligations to the notifying authority with regard to issuing, refusing, restricting, suspending and withdrawing certificates; and of all circumstances affecting notification (if applicable); ▪ Information (on request) to the competent authorities regarding conformity assessment activities, other activities, subcontracts (if applicable); ▪ Information to other notified bodies about negative and (on request) positive results of conformity assessments (if applicable); ▪ Maintenance of list of certified test objects; ▪ Provide information, upon request, about the validity of a given certification. <p>The performance of individual tasks may be delegated by the heads to other certification body personnel. However, the</p>

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

Certification conditions PED, SPVD*Certification conditions PED, SPVD***Legal Scope:**

TÜV Rheinland Polska Sp.zo.o.

Business Scope:

I.01 Pressure Equipment

Process Scope:

6.3 Service Delivery

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

NOTE: This procedure will apply from the moment of changes in the scopes of accreditation number AK 025, AC 141.

1. Process Objectives

The determination of a uniform detailed rules of conduct in carrying out the evaluation of:

- pressure equipment and assemblies, pressure equipment manufacturer's quality assurance systems and permanent joining procedures by TÜV Rheinland Polska Sp. z o.o. Notified Body 2627 for Pressure Equipment according to Directive 2014/68/EU,
- simple pressure vessels by TÜV Rheinland Polska Sp. z o.o. Notified Body 2627 for Simple pressure vessels according to Directive 2014/29/EU.

These certification conditions are an integral part of the contract.

2. Principles, Terms and Abbreviations

Terms/Abbreviations	Description
Certification Body	TÜV Rheinland Polska Sp. z o.o. Notified Body 2627
Applicant	Interested economic player involved in the manufacture of pressure equipment/assembly
Conformity assessment	Means the process demonstrating that the essential safety requirements of this Directive relating to the product have been met (from the directive);
Test object	a) Pressure equipment/ assemblies b) Pressure equipment manufacturer's quality assurance system c) Permanent joining procedure d) simple pressure vessels

Certification conditions PED, SPVD *Certification conditions PED, SPVD*

Terms/Abbreviations	Description
Certification Program	Directive 2014/68/EU "PED" Directive 2014/29/EU "SPVD"
Test plan	a) Inspection Test Plan (ITP) - the purpose of an ITP is to record all requirements related to each step within a supply chain or manufacturing process. The ITP also identifies standards and acceptance criteria of the sampling, tests, inspection and document review. ITP is under the responsibility of applicant b) Audit plan – the purpose of an audit plan is to record all actions which have to be proceed during QM system audit, audit plan is prepared by Certification Body c) Generic plan applicable to all approval of permanent joining procedure - WPQR acc. EN ISO 15607 annex C and EN ISO 15614-1/EN ISO 15613

3. Scope of Application

These certification conditions apply to the following body:

- Notified Body for pressure equipment 2627 TÜV Rheinland Polska Sp. z o.o.
- Notified Body for simple pressure vessels 2627 TÜV Rheinland Polska Sp. z o.o. (hereinafter referred to as "Certification Body" or "Notified Body").

The certification body offers interested economic players involved in the manufacture of pressure equipment or simple pressure vessels and making it available on the market of the European Union (hereinafter referred to as "applicants") the following services in accordance with :

- in the field of pressure equipment 2014/68/EU (PED) in conjunction with the selected procedure (modules),
- for simple pressure vessels 2014/29/EU (SPVD) in conjunction with the selected procedure (modules).

Details are provided in the table below.

Directive	Module	Accreditation standard	NoBo number	Accreditation number
Conformity assessment of pressure equipment, pressure equipment assemblies				
2014/68/EU (PED)	A2 - Internal production control plus supervised pressure equipment checks at random intervals	PN-EN ISO/IEC 17020	2627	AK 025
	B - EU-type examination - production type	PN-EN ISO/IEC 17065	2627	AC 141
	B - EU-type examination – design type	PN-EN ISO/IEC 17065	2627	AC 141
	C2 - Conformity to EU-type, based on internal production control plus supervised	PN-EN ISO/IEC 17065	2627	AC 141

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	pressure equipment checks at random intervals conformity to type based on internal production control and supervised inspection of pressure equipment at random intervals,			
	F - conformity to type based on pressure equipment verification,	PN-EN ISO/IEC 17065	2627	AC 141
	G - conformity based on unit verification	PN-EN ISO/IEC 17065	2627	AC 141
Conformity assessment of the manufacturer's quality assurance systems				
2014/68/EU (PED)	D - conformity to type based on quality assurance of the production process	PN-EN ISO/IEC 17065	2627	AC 141
	D1 - quality assurance of the production process	PN-EN ISO/IEC 17065	2627	AC 141
	E - conformity to type based on quality assurance of the pressure equipment	PN-EN ISO/IEC 17065	2627	AC 141
	E1 - quality assurance of control and testing of finished pressure equipment	PN-EN ISO/IEC 17065	2627	AC 141
	H - compliance based on full quality assurance	PN-EN ISO/IEC 17065	2627	AC 129
	H1 - compliance based on full quality assurance and design examination	PN-EN ISO/IEC 17065	2627	AC 141
Approval of Permanent joining procedures				
2014/68/EU (PED)	Approval of Permanent joining procedures in accordance with point 3.1.2 directive 2014/68/EU	PN-EN ISO/IEC 17020	2627	AK 025
Conformity assessment of simple pressure vessels				
2014/29/EU (SPVD)	B - EU-type examination (production type)	PN-EN ISO/IEC 17065	2627	AC 141
	B - EU-type examination (design type)	PN-EN ISO/IEC 17065	2627	AC 141
	C1 - Conformity to type based on internal production control and testing of tanks under supervision	PN-EN ISO/IEC 17065	2627	AC 141
	C2 - conformity to type based on internal production control and supervised inspection of pressure equipment at random intervals	PN-EN ISO/IEC 17065	2627	AC 141

- The following rules and regulations are applicable:
 - Directive 2014/68/EU (implemented in Poland by the Regulation of the Ministry for Economic Development of 11 July 2016 as regards the requirements for pressure equipment and pressure equipment assemblies),
 - Directive 2014/29/EU (implemented in Poland by the Regulation of the Ministry for Economic Development of 2 June 2016 as regards the requirements for simple pressure vessels),

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- the code of practice selected by the applicant (harmonised standard such as EN 13445 or other non-harmonized technical specification such as AD 2000).
- The “Certification program” 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 harmonised 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 pressure equipment but merely the user of this programme.
- Inspections and conformity assessments must be carried out on pressure equipment, pressure vessels during their manufacture (design phase and production phase) by the Certification Body, in accordance with the requirements of the applicable regulations.
- The manufacturer draws up a written declaration of conformity and marks each model of pressure equipment, pressure vessel with the CE mark and the identification number of the notified body on the basis of the notified body's certificate of conformity relating to the relevant conformity assessment module.

4. Process Flow

4.1 Application

The applicant may approach the Certification Body to perform the assessment by submitting an application on an approved form or by other equivalent means. Approved applications and a description of the certification process are posted on the Body's website.

For individual activities, the approved applications are the following documents:

No.	Scope	Number of document
a)	Conformity assessment of pressure equipment/assemblies	T0.0 MS-0034360 - Application PED Products
b)	Conformity assessment of simple pressure vessels	T0. MS-0043906 - Application SPVD
c)	Conformity assessment of manufacturer's quality assurance systems	T0. MS-0045597 Application PED System
d)	Approval of permanent joining procedures - annex 1 p. 3.1.2 Directive 2014/68/EU	T1-MS-0035119 Preliminary Welding Procedure Specification (pWPS) T4-MS-0035119 Preliminary Brazing Procedure Specification (pBPS)

The applicant shall attach documentation unequivocally 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:

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- Company name, address, contact details, contact partner, number of employees (if applicable),
- Type of test object (module, module combination / WPQR/BPAR),
- Other data required by respective module – see annex III directive 2014/68/EU or annex II directive 2014/29/EU (if applicable).

In the case of taking over certification (module D, D1, E, E1, H, H1), the Client should, at the latest before the assessment, submit full documentation from previous audits in order to prepare an individual audit programme, taking into account the current certification cycle and appropriate audit time.

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 Certification Body.

All information about services according to 2014/68/EU or 2014/29/EU are available at the Certification Body's web page including those certification conditions with related templates of application.

The precondition for commencing cooperation with the Notified Body is concluding a contract for conformity assessment including acceptance of those certification conditions. The contract for conformity assessment according to 2014/68/EU or 2014/29/EU remains valid for every subsequent application for conformity assessment.

The manufacturer may not apply for the conformity assessment to another notified body for module B - production type and B - design type, D, D1, E, E1, H, H1. Signing the contract shall be read as written declaration that the same application has not been lodged with any other notified body.

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.

If an applicant uses self-selected methods, which are not covered by harmonized standards, in particular in relation to the design, manufacture and testing of pressure equipment or assemblies, the Notified Body, at the application review stage, shall carry out appropriate tests to verify that the applicant's solutions are convergent (non-contradictory) with the essential safety requirements of Directive 2014/68/EU.

The applicant's use of a set of rules defining the essential safety requirements adopted in a Member State of the European Union or abroad, which are legally subject to arbitrary acceptance as reference documents by other notified bodies shall be accepted by the Notified Body TÜV Rheinland Polska Sp. z o.o. as meeting the essential requirements of Directive 2014/68/EU or 2014/29/EU.

A test laboratory designated by the manufacturer to carry out tests necessary in conformity assessment of a pressure equipment must meet the applicable requirements of EN ISO/IEC 17025 standard (see MS-0013485). Evidence confirming that the above requirements are met is the Certificate issued by an Accreditation Body or Certificate of Recognition issued by other Notified Bodies or the Central Laboratory for Technical Inspection.

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Prior to the commencement of the conformity assessment process, documents must be provided to confirm that the requirements have been met, otherwise the laboratory will be subject to a separate assessment as part of the inspection activities.

4.2 Evaluation

4.2.1 Requirements for planning:

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

- a) ITP plan for conformity assessment of pressure equipment/assemblies/pressure vessels,
- b) Audit plan for conformity assessment of manufacturer's quality assurance systems,
- c) General plan for the evaluation activities for approval of permanent joining procedures.

- Step 1 - inspection on site
 - supervision of the welding process in accordance with the pWPS/ pBPS
 - check of related documentation, equipment and personnel qualifications

- Step 2 - Laboratory tests

Time for evaluation is estimated according below general rules.

Evaluation time				
Thickness range	t ≤ 10	10 < t ≤ 30	30 < t ≤ 50	t > 50
Welding - min. [h]	2	4	6	8
Total time - min. [h]	6	8	10	12

4.2.2 Requirements for technical documentation

The scope of the required documentation is presented in the following table.

A2 ¹	B0 ^{1,2}	Bd ^{1,2}	C ²	C1 ²	C2 ^{1,2}	D ¹	D1 ¹	F ¹	E1 ¹	F ¹	G ¹	H ¹	H1 ¹	WPQR ¹ BPAR	Technical documentation
X	X	X					X	X	X	X		X			General description of a pressure equipment (type)
X	X	X					X	X	X	X		X			Layout drawing of the design and drawings and schemes of specific elements, subassemblies and circuits (the documentation should also include drawing and scheme list)
X	X	X					X	X	X	X		X			Descriptions and clarifications necessary for comprehending the drawings and schemes including the description of pressure equipment operation
X	X	X					X	X	X	X		X			Specification of harmonised standards used fully or partly and descriptions of solutions adopted in order to meet the basic requirements if the standards have not been used
X	X		X	X	X ²		X	X	X	X		X			Test protocols
X	X	X					X	X		X		X			Results, especially of design calculations and the conducted examinations
X	X	X	X	X					X	X					Information regarding qualifications or entitlements of the personnel performing the assembly or non-destructive tests of inseparable element connections affecting the pressure resistance

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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 CE mark is affixed by the applicant, then the applicant is entitled to affix the Notified Body's identification number in combination with the CE mark to his products. The identification number of TÜV Rheinland Polska Sp. z o.o. is 2627. A prerequisite is, however, that the successful certification according to the specified modules / procedures / articles within the scope of the Directive has been accomplished.

The certificates and certifications certify that the 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.

Certificate validity:

- In terms of the conformity assessment procedure under module A2, the EC Certificate is valid for 1 year
- In terms of the conformity assessment procedure under module C1, the Certificate is valid for 1 year
- In terms of the conformity assessment procedure under module C2, the Certificate is valid for 1 year
- In terms of the conformity assessment procedures under module B - production type, EU-type Examination Certificate is valid for 10 years
- In terms of conformity assessment procedures under module B - design type, EU Design Examination Certificate is valid for 10 years
- In terms of the conformity assessment procedures under module F, the Certificate of Conformity is valid for a given product
- In terms of the conformity assessment procedures under module G, the Certificate of Conformity is valid for a given product
- In terms of the conformity assessment procedures under module D, Certificate is valid for 3 years
- In terms of the conformity assessment procedures under module D1, Certificate is valid for 3 years
- In terms of the conformity assessment procedures under module E, Certificate is valid for 3 years
- In terms of the conformity assessment procedures under module E1, Certificate is valid for 3 years
- In terms of the conformity assessment procedures under module H, Certificate is valid for 3 years
- In terms of the conformity assessment procedures under module H1, Certificate is valid for 3 years
- In terms of the approval of permanent joining procedures, Certificate is valid for an unlimited period.

4.5 Surveillance

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In the case of conformity assessment procedures for modules A2, C1, C2, D, D1, E, E1, H, H1:

The process is supervised through surveillance audits and unannounced visits. The results of the visits are reviewed and the certification 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:

- carry out an unannounced visit,
- suspend or withdraw certification,
- limit the scope of certification,
- follow-up audits (if applicable).

Unannounced visits:

The following factors are considered in defining individual visit control system (frequency of unexpected visits) for client: the category of the pressure equipment, the results of previous surveillance visits, the need to follow up corrective actions, special conditions linked to the approval of the system, where applicable, significant changes in manufacturing organisation, policy or techniques and other directive requirements.

Unannounced visits taking place at least once every year and for pressure equipment (referred in point (i) of point (a) of Article 4(1), first indent of point (ii) of point (a) of Article 4(1) and point (b) of Article 4(1)) categories II and IV (applicable to module D, E, H, H1) in first year of production at least 2 visits in order to perform the final assessment.

Unannounced visits may also be carried out in the event of reasonable doubts as to the fulfilment of the terms and conditions of this contract by the Applicant, the receipt of information about complaints regarding certified products to verify the effectiveness of the corrective actions taken by the Applicant.

In justified cases, control tests of product samples collected from the market. The Applicant shall be informed about a unannounced visit not later than one day before the inspection.

4.8 Withdrawing, restrictions, suspension, revocation

In the case of conformity assessment procedures for modules D, D1, E, E1, H, H1:

Notified body inform the notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Notified body inform other notified bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

In the case of conformity assessment procedures for modules B - production type, B - design type.

Notified body inform its notifying authority concerning the EU-type examination certificates – production/design type and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make

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available to the notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Notified body inform other notified bodies concerning the EU-type examination certificates – production/design type and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates – production/design type and/or additions thereto. 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 EU-type examination certificate – production/design type, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

4.9 Duties and responsibility of the Certification Body

4.9.1 Obligation of the Certification Body

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

The Notified Body shall inform the relevant notifying authority about EU-type examination certificates – production type / EU-type examination certificates – design type or any supplements to these documents that it has issued or withdrawn and, periodically or on demand, shall make available to relevant notifying authorities a list of certificates or any supplements to these certificates that were rejected, suspended or in any other way restricted.

The Notified Body shall inform the notifying authority about each rejection, restriction, suspension or withdrawal of certificates;

The Notified Body shall share, with other notified bodies carrying out similar activity in scope of conformity assessment of the same pressure devices, information regarding issues associated with negative results of conformity assessment and, on demand, also information regarding issues associated with positive test results.

The Notified Body shall inform other notified bodies about EU-type examination certificates – production type / EU-type examination certificates – design type or any supplements to these documents that it has refused to issue, withdrawn, suspended or in other way restricted and, on demand, about certificates or any supplements to these documents that it has issued.

The Notified Body, on request from other notified bodies and member states, shall share copies of EU-type examination certificates – production type / EU-type examination certificates – design type or any supplements to these documents. On request of the European Commission and member states, the Notified Body shall share a copy of the technical documentation and the results of examinations conducted by the Applicant. The Applicant shall store a copy of the EU-type examination certificates – production type / EU-type examination certificates –

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design type, annexes as well as technical documentation including documents submitted by the Applicant until the expiry of the certificate validity.

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 demand, about activities undertaken in relation to conformity assessment that are subject to notification and about other executed tasks including transborder activity and subcontracting.

The Notified 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 demand, about activities undertaken in relation to conformity assessment that are subject to notification and about other executed tasks including transborder activity and subcontracting.

The Certification Body shall inform the Applicant or their representative upon every request about the requirements of Directive 2014/68/EU.

The Certification 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 rigour and the level of protection required for product conformity with the regulations of Directive 2014/68/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 Certification Body website.

In case of module C1, C2 of SPVD directive the notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

4.9.5 Subcontracting

The Certification Body may, with the consent of the Applicant, employ qualified subcontractors to carry out laboratory tests and other parts of tasks related to conformity assessment, such as carrying out inspections or audits.

The Certification Body shall ensure that, in the above mentioned case, the applicable requirements of relevant standards and the requirements of Directive 2014/68/EU article 27 or Directive 2014/29/EU article 23 have been met.

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The policy of the Certification Body relying on tests performed in production plants or external laboratories obliges the 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 Certification 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 Certification 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 Certification Body not later than within 3 months (this refers to the conformity assessment procedures for modules A2, C1, C2, D, D1, E, E1, H, H1.

Prior to the commencement of the inspection at the pressure equipment/vessel 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 signalisation 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. Local Specifications

N/A

7. Attachments

N/A

8. Related Documents

MS-0034720 - Certification conditions BS I

9. External Reference Documents

Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment

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Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels

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

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

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

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

DACW-01 Accreditation of Product Certification Bodies. Specific requirements

DA-11 Accreditation of conformity assessment bodies for notification purposes

DAN-03 Accreditation of conformity assessment bodies for notification purposes in according to Directive 2014/29/EU and Directive 2014/68/EU

DA-06 Ensuring measurement consistency policy

IAF/ILAC-A5

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

Regulation of the Ministry for Economic Development of 11 July 2016 as regards the requirements for pressure equipment and pressure equipment assemblies

Regulation of the Minister Of Development of 2 June 2016 on simple pressure vessels

Certification Conditions FPC**Legal Scope:**

TÜV Rheinland Polska Sp.zo.o.

Business Scope:

I.01 Pressure Equipment

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.

1. Objectives

The determination of uniform detailed rules of conduct in carrying out the inspection and certification of manufacturers of construction products in accordance with the European Construction Products Regulation (EU) No. 305/2011 by TÜV Rheinland Polska Sp. z o.o. Notified Body 2627 for construction products within the framework of accreditation AC 141.

The certification conditions are an integral part of the contract.

2. Terms and Abbreviations

Terms/Abbreviations	Description
Test object	Construction products
Applicant	Interested economic player involved in the manufacture of construction products. Whenever the term “applicant” is used in those certification conditions, it applies to both the “applicant” and the “client”, unless otherwise specified.
Certification Body	Notified Body for construction products TÜV Rheinland Polska Sp. z o.o. (Notified Body No. 2627)
Certification Program	Regulation (EU) No 305/2011 (Construction Products Regulation, or “CPR”)
FPC	Factory Production Control
CPR	Wherever Regulation (EU) No 305/2011 (CPR) is referred to in this document, it shall be understood as Regulation (EU) No 305/2011 (CPR), as amended by Regulation (EU) No 568/2014.
Certification of material manufacturer	Certification of FPC of material manufacturer

3. Scope of Application

These certification conditions apply to the following conformity assessment bodies of:

- Notified Body for construction products 2627 TÜV Rheinland Polska Sp. z o.o. (hereinafter referred to as “Certification Body” or “Notified Body”).

Certification Conditions FPC

This document is applicable to manufacturers of construction products within the meaning of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

FPC

This document covers the scope of assessment and inspection of constancy of performance of construction products in relation to their essential characteristics, in accordance with the system 2+ "Factory Production Control Certification" set out in Annex 5 to the CPR.

Product group

Group of certified products in accordance with Annex IV to the CPR

Group code: 20,

Product group: Structural metallic products and auxiliary products,

Product: Steel or aluminum structural elements,

Product: Metallic base materials,

Product: Welding filler metals

Criteria for certification

EN 1090-1 Execution of steel and aluminum structures - Part 1: Principles of conformity assessment of structural elements.

EN 1090-2 Construction of steel and aluminum structures - Part 2: Technical requirements for steel structures.

EN 1090-3 Construction of steel and aluminum structures - Part 3: Technical requirements for aluminum structures.

EN 1090-5 Execution of steel structures and aluminium structures. Technical requirements for cold-formed structural aluminium elements and cold-formed structures for roof, ceiling, floor and wall applications.

EN 1090-4 Execution of steel structures and aluminium structures. Technical requirements for cold-formed structural steel elements and cold-formed structures for roof, ceiling, floor and wall applications.

EN 10025-1 Hot rolled products of structural steels - Part 1: General technical delivery conditions

EN 10210-1 Hot finished structural hollow sections of non-alloy and fine grain steels - Part 1: Technical delivery conditions

EN 10219-1 Cold formed welded structural hollow sections of non-alloy and fine grain steels - Part 1: Technical delivery conditions

EN 10340 Steel castings for structural uses

EN 10343 Steels for quenching and tempering for construction purposes - Technical delivery conditions

EN 10088-4 Stainless steels - Part 4: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for construction purposes

EN 10088-5 Stainless steels - Part 5: Technical delivery conditions for bars, rods, wire, sections and bright products of corrosion resisting steels for construction purposes

Certification Conditions FPC

EN 15088 Aluminum and aluminum alloys - Structural products for construction works - Technical conditions for inspection and delivery

EN 15048-1 Non-preloaded structural bolting assemblies -- Part 1: General requirements

EN 14399-1 High-strength structural bolting assemblies for preloading -- Part 1: General requirements

4. Principles

The manufacturer shall carry out:

- a) assessment of the performance of the construction product on the basis of tests (including sampling), calculations, tabulated values or descriptive documentation of the product
- b) factory production control
- c) testing of samples taken at the factory by the manufacturer in accordance with the prescribed test plan

The Certification Body shall decide whether to issue, refuse, restrict, suspend or withdraw the certificate of conformity of factory production control on the basis of the results of the following assessments and inspection carried out by this Body:

- a) initial inspection of the manufacturing plant and of factory production control
- b) to continue the surveillance, assessment and evaluation of factory production control

Each certification process shall be conducted in accordance with the following process description.

4.1 Application Review

Manufacturer may apply for the conformity assessment according to the conformity certification process of Factory Production Control by filing an application available on the website www.tuv.com/zalaczniki or in another equivalent way. The Applicant shall attach documentation unequivocally identifying the subject of assessment indicated in the application form.

Fees for the activities associated with the certification process are calculated according to the real allocation of time necessary for performing the evaluation. The fees are determined on the basis of a calculation prepared by Certification Body.

All information about certification process is available at the Certification Body's web page including those certification conditions with related template application.

The precondition for commencing cooperation with the Certification Body is concluding a contract including those certification conditions. A contract template is available at www.tuv.com/zalaczniki.

Prior to the assessment, the conditions of execution are agreed with the Applicant and the completeness of the conformity assessment application is reviewed to ensure that the information provided is sufficient for the assessment and that the Certification Body has the necessary competencies and means to carry out the assessment.

4.2 Evaluation

The date of the inspection is agreed with the Applicant and the scope of the inspection presented in an inspection plan. The certification shall be carried out at the manufacturing plant/s indicated by Applicant.

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The inspection begins with an opening meeting with the staff responsible for the different types of processes to be assessed.

The scope of the initial inspection includes activities related to design and/or execution of the structure through control and assessment in accordance with the requirements of Criteria of certification (see point 3).

The inspection shall be carried out using methods for collecting information such as interview, observation of processes and activities, review of documentation and records.

The conclusions of the inspection shall be presented at the closing meeting and the results of the inspection are summarised in a report.

4.3 Review and certification decision

The decision to grant certification shall be a condition for issuing certification documents such as a certificate of conformity of factory production control and if it concerns a welding certificate of competence.

Certification is indefinite, provided that supervision of the Company's Production Control by the Company is maintained at specified intervals between inspections.

The certification shall be valid subject to the validity of the issue of the harmonized standard for which the certification document has been issued or to the production conditions in the factory or to the factory production control itself being substantially altered.

When a manufacturer has not complied with the certification requirements, the Certification Body shall require the manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4.4 Certificate, test mark

The Certificate of Conformity shall contain the following information

- name, address and number of the Certified Body
- the date on which certification was granted
- the name and address of the manufacturer
- scope of certification
- conditions and period of validity of certification
- the number of the certificate
- name and signature of the person responsible for the Certificate Authorization
- date of next surveillance

In case Factory Production Control certification, in accordance with EN 1090-1 additional The Welding Qualification Certificate is issued by Certification Body, which contains the following information*

- scope and appropriate normative reference
- execution class

Certification Conditions FPC

- welding processes
- base materials

* scope is not included by certification or notification .

If procedures are applied under which the CE mark is affixed by the Applicant, then the Applicant is entitled to affix the Notified Body's identification number in combination with the CE 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/articles within the scope of the Regulation has been accomplished.

The model of the CE marking and its contents are specified in Regulation (EC) No 765/2008 and in the CPR Regulation.

In addition to the certificate, the Certification Body can also issue a certificate mark (test mark) at an additional cost. Example for EN 1090-1:

**4.5 Surveillance**

Continuous supervision and assessment of Factory Production Control

Within a period of 3 months before the surveillance term indicated in the certification documents, the manufacturer may lodge an application with a Body for a surveillance inspection. The Body conducts activities within the framework of continuous supervision, assessment and evaluation of the factory production control.

The Body shall carry out surveillance inspections in accordance with the requirements of the reference standard to determine:

- a) the operation of procedures for periodically evaluating and reviewing compliance with the relevant plant production control laws and regulations
- b) the actions taken in response to the nonconformities and observations identified during the last inspection

The first surveillance inspection shall be carried out within 12 months of the initial inspection.

Subsequent supervision inspections in scope structural elements group, shall be carried out in accordance with Table B.3 of EN 1090-1, taking into account the requirements of clause B.4.1. and B.4.4.

In case of metallic base materials and welding filler metals, surveillance inspection are once a year.

Each surveillance inspection shall be preceded by an inspection plan specifying the scope of the surveillance inspection.

Certification Conditions FPC

The purpose of surveillance inspection is to confirm the maintenance of the monitoring system of Factory Production Control

During the period of validity of the certificate, the Body shall perform supervision in order to ensure that the Applicant places on the market products meeting the requirements of reference documents being the basis for certification and correctly applies the certificate and CE marking.

If the interval between inspections is 2 or 3 years (for structural elements), the applicant shall submit annually to the Body a manufacturer's declaration according to clause B.4.3 of EN 1090-1.

Special inspection/special inspection with short notice

The Certification Body reserves the right to carry out special inspections in addition to the planned surveillance inspections. The special inspection may be conditioned by changes in the reference criteria, the certification scheme, the necessity to verify the corrective and corrective actions to the identified non-conformities, a declaration of the manufacturer indicating changes which may affect the fulfilment of the requirements.

In case of a complaint regarding non-compliance with certification requirements, the Body reserves the right to conduct an inspection with a short notice period.

Conditions for changing the notified body

In order to undertake a factory production control assessment of a customer who holds a valid certificate of another notified body, it is necessary to ensure that the client has terminated the contract with another notified body.

Regardless of whether the client was previously certified an assessment in the form of certification (initial inspection of the production site and factory production control) should be carried out.

Subcontracting of processes subject to inspection by the applicant

In case the applicant subcontracts totally or partially the processes subject to inspection to another company, it may be necessary to perform part of the inspection at the subcontractor. If a welding process is subcontracted, a visit at the subcontractor is mandatory. In case of other processes, the necessity of the visit depends on the influence of the given process on the conformity of the construction product with declared performance, if it is significant, an inspection at the subcontractor's is necessary. A case by case approach is applied. If the applicant's subcontractor is certified by TÜV Rheinland Polska Sp. z o.o. to the evaluated scope, a visit at the subcontractor may be omitted.

This applies to the initial inspection, however, the certification body takes into account changing circumstances. In case a new subcontractor is included in the certified ZKP system, the above analysis is also carried out.

4.6 Withdrawing, restrictions, suspension, revocation

The Body reserves the right to publish information on withdrawal of certification on its website Certipedia and to inform other notified bodies.

Certification Conditions FPC

The Body shall have the right to withdraw the Certificate and/or terminate the agreement without notice in the event of repeated irregularities being detected which indicate that the factory production control fails to comply with the provisions of the technical specifications.

In this case, the manufacturer shall lose the right to affix the CE marking to the construction products.

4.7 Duties and responsibility of the Certification Body

4.7.1. Obligation of the Certification Body

The Body shall make available information on certified products at Certipedia by publishing the certificate.

The Body undertakes to deal with information in its possession concerning Applicant as well as with confidential information (except for keeping secret from the competent authority) and to process it only to the extent agreed upon.

Applicant may release the Body from its obligation of confidentiality. The staff of the Body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks, except vis-à-vis the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

In the event of changes in production processes, the Body shall, on the basis of the declaration of the manufacturer, decide to carry out a special inspection at the Applicant's premises. The unit is obliged to inform Applicant about the result of the decision made. The notification shall contain the grounds on which the decision is based.

The Body must inform the notifying authority:

- refusing, limiting or revoking certificates,
- any circumstances affecting the scope of and conditions for notification;
- any request for information on assessment and/or verification activities of constancy of performance carried out which has been received from market surveillance authorities;
- on request - third party tasks in accordance with the systems of assessment and verification of constancy of performance carried out within the scope of the notification and any other activity performed, including cross-border activities and subcontracting.

The Body shall undertake to provide the other notified bodies, carrying out similar conformity assessment activities covering the same products with information on issues relating to negative and, on request, positive conformity assessment results.

The Body shall carry out its assessment in a proportionate, transparent and proportionate manner with regard to the producer, avoiding creating unnecessary burdens for economic operators.

The Body performs its tasks taking into account the size of the enterprise, the sector in which the enterprise operates and its structure, the complexity of the technologies used in production and the mass or serial nature of the production process. While respecting the degree of rigor and the level of protection required for the compliance of the product with the legal provisions.

4.7.2. Subcontracting

Certification Conditions FPC

The Certification Body do not subcontract conformity assessment activities within the scope of carrying out those certification conditions.

4.8 Rights and obligations of the applicant

4.8.1. Obligations of the Applicant

Applicant is obliged to permanently meet all requirements specified in this certification scheme of factory production control in the system 2+ in accordance with the requirements of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEG and the harmonized standards.

Before proceeding with the inspection, Applicant shall provide instruction on the hazards that may occur, on the collective and personal protective equipment to be used, and on how to use it, and on how to proceed in the event of such hazards.

In case the applicant subcontracts in whole or in part the significant processes subject to inspection to another company, it is obliged to provide the certification body a possibility to carry out the inspection at the subcontractor. Significant process means a process of which the controlling is likely to have a significant influence on the conformity of the construction product with the declared performance. A significant process is welding.

4.8.2. Information about changes

Applicant is obliged to send the manufacturer's declaration of any changes in the scope of the product and production processes or their absence in accordance with harmonized standards.

Applicant shall be obliged to inform the Certification Body without delay of any changes that may affect the ability of the certification requirements, in particular the legal, commercial, organizational or ownership status of the organizational and management structure, modification of the product or production method, contact address or place of production, significant changes in the quality management system.

4.8.3 Responsibility / liability of the Applicant

Financial liability under the Act on Conformity Assessment and Market Supervision, Chapter 6a Financial penalties are borne solely by the Applicant.

5. Roles & Responsibilities

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

6. Specifications

N/A

7. Attachments

N/A

8. Related Documents

Certification Conditions FPC

MS-0034720 - Certification conditions BS I

9. External Reference Documents

REGULATION (EU) No 305/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC

Commission Delegated Regulation (EU) No 568/2014 of 18 February 2014 amending Annex V to Regulation (EU) No 305/2011 of the Euro. Parliament and of the Council as regards the assessment and verification of constancy of performance of construction products

Commission Regulation (EU) No 574/2014 of 21 February 2014 amending Annex III to Regulation (EU) No 305/2011 of the European Parliament and of the Council as regards the model to be used for drawing up the declaration of performance of construction products

Commission Decision No 98/214/EC of 9 March 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural metallic products and ancillaries

Commission Decision No 2001/596/EC of 8 January 2001 amending Decisions 95/467/EC, (...) on the procedure for attesting the conformity of certain construction products pursuant to Article 20 of Council Directive 89/106/EEC

Act of 7 July 1994 - Construction Law

Act of 16 April 2004 on construction products

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

Regulation of the Minister of Development of 22 October 2016 on the method of determining fees for activities related to mandatory conformity assessment of products.

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

EN ISO/IEC 17067 Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes

DACW-01 Accreditation of Product Certification Bodies. Specific requirements

DAN-01 Accreditation of conformity assessment bodies for activities covered by Regulation (EU) No 305/2011 of the European Parliament and of the Council (CPR)

DA-11 Accreditation of conformity assessment bodies for notification purposes

Certification Conditions FPC

EA-2/17 M - EA Document on Accreditation for Notification Purposes

NB-CPR/17/722 - Position Paper / Guidance to notified bodies on the Assessment and Verification of Constancy of Performance under the Construction Products Regulation

NB-CPR/14-612 - Position Paper / Issuance of certificates under CPR

NB-CPR/16/684 - Position Paper / Frequencies for the surveillance, assessment and evaluation of factory production control

NB-CPR/17-744 - Position Paper / Subcontracting of NB work

NB-CPR/20-852 - Maintaining certificates during the COVID 19

NB-CPR/14-612 Issuance of certificates under CPR

NB-CPR/13-567 What FPC certification means at AVCP system 2+

NB-CPR/17/724 The role of notified bodies in relation structural construction products in AVCP system 2+

NB-CPR/SG17/09/069 Certification of FPC of steel and aluminium structural components to EN 1090-1

NB-CPR/SG17/16/106 Position Paper Equalisation of Notified Bodies' methods for the estimation of duration of audits to EN 1090-1

EN 1090-1 Execution of steel structures and aluminium structures - Part 1 Requirements for conformity assessment for structural components

EN 1090-2 Execution of steel structures and aluminium structures - Part 2 Technical requirements for steel structures

EN 1090-3 Execution of steel structures and aluminium structures - Part 3 Technical requirements for aluminium structures

EN 1090-4 Execution of steel structures and aluminium structures. Technical requirements for cold-formed structural steel elements and cold-formed structures for roof, ceiling, floor and wall applications

EN 1090-5 Execution of steel structures and aluminium structures. Technical requirements for cold-formed structural aluminium elements and cold-formed structures for roof, ceiling, floor and wall applications

EN 10025-1 Hot rolled products of structural steels - Part 1 General technical delivery conditions

EN 10210-1 Hot finished structural hollow sections of non-alloy and fine grain steels - Part 1 Technical delivery

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conditions

EN 10219-1 Cold formed welded structural hollow sections of non-alloy and fine grain steels - Part 1 Technical delivery conditions

EN 10340, EN 10340/AC Steel castings for structural uses

EN 10343 Steels for quenching and tempering for construction purposes - Technical delivery conditions

EN 10088-4 Stainless steels - Part 4 Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for construction purposes

EN 10088-5 Stainless steels - Part 5 Technical delivery conditions for bars, rods, wire, sections and bright products of corrosion resisting steels for construction purposes

EN 15088 Aluminium and aluminium alloys - Structural products for construction works - Technical conditions for inspection and delivery

EN 13479 Welding consumables - General product standard for filler metals and fluxes for fusion welding of metallic materials

EN 14399-1 High-strength structural bolting assemblies for preloading - Part 1 General requirements

EN 15048-1 Non-preloaded structural bolting assemblies - Part 1 General requirements

Certification conditions EN ISO 3834**Legal Scope:**

TÜV Rheinland Polska Sp.zo.o.

Business Scope:

I.01 Pressure Equipment

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.

1. Objectives

The determination of uniform detailed rules of conduct in carrying out the conformity assessment of evaluation of welding processes according to EN ISO 3834 by TÜV Rheinland Polska Sp. z o.o. certification body.

These certification conditions are an integral part of the contract.

2. Terms and Abbreviations

Terms/Abbreviations	Description
Test object	Welding process
Applicant	Interested manufacturers related to welding process. Whenever the term "applicant" is used in those certification conditions, it applies to both the "applicant" and the "client", unless otherwise specified.
Certification body	TÜV Rheinland Polska Sp. z o.o.
Certification program	This document. Certification Conditions EN ISO 3834
Inspection	For the reason of the difference in the naming (audit, inspection) in reference documents the term "inspection" is used, it applies to both the "audit" and the "inspection".

3. Scope of application

These certification conditions apply to the certification body for Welding Manufacturers owned by TÜV Rheinland Polska Sp. z o.o. (hereinafter referred to as "certification body").

The certification body offers interested manufacturers responsible for the welding production (hereinafter referred to as "Applicants") the following services (certification) evaluation of welding processes in accordance with EN ISO 3834.

The scope of the performed certification is accredited by Polish Accreditation Centre. Accreditation number AC 141.

The certification program regulates certification and surveillance inspection for Applicants providing welding processes in production range:

Certification conditions EN ISO 3834

- pressure equipment or of components for pressure equipment,
- steel constructions or of components for steel constructions,
- railway vehicles or of components for railway vehicles,
- components for machine constructions.

The certification service - evaluation of welding processes in accordance with EN ISO 3834 is not regulated by law. The "Certification program" is set out by rules and regulations described in this document, based on standards EN ISO/IEC 17065, EN ISO/IEC 17067 (certification scheme type 6), EN ISO 3834-1-5 and guidelines CEN ISO/TR 3834-6, EA-6/02. The certification body is the owner of the certification program.

Evaluation criteria

PN-EN ISO 3834-2:2007
EN ISO 3834-2:2005
PN-EN ISO 3834-3:2007
EN ISO 3834-3:2005
PN-EN ISO 3834-4:2007
EN ISO 3834-4:2005
PN-EN ISO 3834-2:2021-09
EN ISO 3834-2:2021
PN-EN ISO 3834-3:2021-09
EN ISO 3834-3:2021
PN-EN ISO 3834-4:2021-09
EN ISO 3834-4:2021

4. Principles**4.1 Application Review**

The Applicant may apply for the certification to EN ISO 3834 by filing an 3834 application (T4.1 MS-0034793) or in equivalent way. The Applicant shall attach documentation unequivocally identifying the subject of assessment indicated in the application form.

Fees for the activities associated with the certification process are calculated according to the real allocation of time necessary for performing the evaluation. The fees are determined on the basis of a calculation prepared by certification body.

All information about evaluation of welding processes in accordance with EN ISO 3834 is available at the certification body's web page including those certification conditions with related template application.

The precondition for commencing cooperation with the certification body is concluding a contract including those certification conditions.

Prior to the assessment, 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 evaluation and that the certification body has the necessary competencies and means to carry out the assessment.

Certification conditions EN ISO 3834

4.2 Evaluation

The date of the inspection is agreed with the Applicant and the scope of the certification presented in the inspection plan. The evaluation shall be carried out in accordance with the inspection plan.

The inspection shall be carried out by conducting interviews, reviewing and analyzing documents, and by direct observation of operations on the Applicant's premises and by inspection of the welded products. It shall assess the correctness of implementation and compliance with EN ISO 3834 in the part indicated in the application.

In order to achieve full compliance with EN ISO 3834 Parts 2, 3 or 4, the Applicant shall apply the documents listed in point 2.2 of Part 5 of EN ISO 3834, or other documents setting out equivalent conditions from a technical point of view, where these documents are referred to in the standards for devices manufactured by the Applicant. It is the responsibility of the Applicant to indicate equivalent technical conditions where documents other than those listed in Part 5 of EN ISO 3834 are used.

The results of the inspection are summarised in a report.

4.3 Review and certification decision

In accordance with Certification conditions BS I (MS-0034720).

4.4 Certificate, test mark

The certificate contains information about the name and address of the entity, date of certification, name and address of the Applicant, scope of certification including the process for which certification was granted, reference standards, validity period.

The certificate shall be issued for a period of validity of 5 years from the date of issue, subject to satisfactory results of surveillance. The certificate is submitted to the Applicant together with an evaluation report.

In addition to the certificate, the certification body can also issue a certificate mark (test mark) at an additional cost.

**4.5 Surveillance**

For the first certification cycle, a surveillance audit is carried out within 12 calendar months (with a 3-month tolerance) of the date of the certification decision. This yearly frequency must be maintained when nonconformities or significant recommendations have been identified that raise doubts about the manufacturer's ability to meet all customer requirements. However, if no nonconformities or significant recommendations have been identified during the audit, the period until the next surveillance audit may be extended to a maximum of 36 months. In case of critical changes in the manufacturer's processes and/or products occur verification of continuing conformity with the EN ISO 3834 have to performed (verification activities: e.g. surveillance audits).

Certification conditions EN ISO 3834

Every year in which a surveillance audit is not carried out and in the case of changes which could have a significant impact on the quality of production, the customer is obliged to submit a declaration [T4.2-MS-0034793].

To this end, the Client must submit a declaration to the certification body y about changes that have taken place:

- change in the organization of the company
- changes in welding supervisory personnel
- modification of welding procedures
- modification of materials, dimensions
- change in the nature of the products manufactured
- changes due to the rules and regulations

This declaration is assessed by the certification body as to whether an additional surveillance inspection is necessary.

Certificates issued under the previous revision of the certification program (MS-0013027), which were issued for a period of 3 years with annual surveillance, shall be retained and the certification program applicable at the time of issue shall apply.

4.9 Duties and responsibility of the certification body**4.9.5 Subcontracting**

The certification body shall not subcontract certification activities within the program area.

4.9.8 Records / register of the test items certified

The certification body shall ensure the archiving of documentation from the process (for at least 2 certification cycles in the case of the surveillance and extension of the certification).

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

Certification conditions EN ISO 3834

9. External Reference Documents

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

EN ISO/IEC 17067 Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes

EA-6/02

DACW-01 Accreditation of product certification bodies

*EN ISO 3834-1 Quality requirements for fusion welding of metallic materials - Part 1
Criteria for the selection of the appropriate level of quality requirements*

*EN ISO 3834-2 Quality requirements for fusion welding of metallic materials - Part 2
Comprehensive quality requirements*

*EN ISO 3834-3 Quality requirements for fusion welding of metallic materials - Part 4
Elementary quality requirements*

*EN ISO 3834-4 Quality requirements for fusion welding of metallic materials - Part 4
Elementary quality requirements*

*EN ISO 3834-5 Quality requirements for fusion welding of metallic materials - Part 5
Documents with which it is necessary to conform to claim conformity to the quality requirements of ISO 3834-2,
ISO 3834-3 or ISO 3834-4*

Certification conditions EN 15085-2, Warunki certyfikacji EN 15085-2

Legal Scope:

TÜV Rheinland Polska Sp.zo.o.

Business Scope:

I.01 Pressure Equipment

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.

1. Objectives

The determination of uniform detailed rules of conduct in carrying out the conformity assessment of organizations related to the production of railway rolling stock in the scope of fulfilment the quality requirements in accordance with the standard EN 15085-2 (PN-EN 15085-2) by TÜV Rheinland Polska Sp. z o.o. Certification Body.

BSI Certification Conditions (MS-0034720) and these EN 15085-2 Certification Conditions (MS-00350033) are an integral part of the contract.

2. Terms and Abbreviations

Terms / Abbreviations	Description
Certification Body	TÜV Rheinland Polska Sp. z o.o.
Certification program	This document. Certification conditions EN 15085-2
Test object	Organisations (welding manufacturers) using welding process for manufacture railway vehicles and/or their parts and organisations which do not perform welding works but design / buy and assemble / buy and further distribute railway vehicles and/or parts of rail vehicles
Applicant	Interested organizations related to the production of railway vehicles and/or their parts, which scope of activity covers the requirements of EN 15085-2. Whenever the term "Applicant" is used in those certification conditions, it applies to both the "Applicant" and the "Client", unless otherwise specified.

Certification conditions EN 15085-2, Warunki certyfikacji EN 15085-2

Terms / Abbreviations	Description
Certification Body	TÜV Rheinland Polska Sp. z o.o.
Certification program	This document. Certification conditions EN 15085-2

3. Scope of application

These certification conditions apply to the Certification Body for Welding Manufacturers owned by TÜV Rheinland Polska Sp. z o.o. (hereinafter referred to as "Certification Body").

The Certification Body offers interested organisations the services of certification with accordance to EN 15085-2.

The scope of the certification performed is accredited by the Polish Accreditation Center (No. AC 141).

The certification program regulates the performance of certification and surveillance in order to approve Applicants in the scope of their compliance with the applied classification level according to EN 15085-2, i.e. CL 1 / CL 2 / CL 3 and type of activity: D – design, P – production, M – maintenance, S – purchase and supply.

The certification service - evaluation of the organisations in accordance with EN 15085-2 is not regulated by the law. The certification program is set out by rules and regulations described in this document, based on standards EN ISO/IEC 17065, EN ISO/IEC 17067 (certification scheme type 6) and series of standards EN 15085. The Certification Body is the owner of the certification program.

Evaluation criteria

PN-EN 15085-2:2007

EN 15085-2:2007

PN-EN 15085-2:2021-03

EN 15085-2:2020

4. Principles**4.1 Application**

The Applicant may apply for the certification according to EN 15085-2 to the Certification Body by submitting the completed application form (T0-MS-0035137). The Applicant shall attach to the application the documents unequivocally identifying the indicated subject of assessment.

In order to prepare the calculation, it is required to provide, at a minimum, information on the evaluation object.

The following details and information about the applicant are required:

Certification conditions EN 15085-2, Warunki certyfikacji EN 15085-2

- customer data (company name, address, contact person, telephone number, website),
- specific type of assessment and certification,
- details of the applicant:
 - personnel / number of employees / number of welders and operators,
 - number of daily production shifts,
 - organization, locations, equipment, production processes,
 - certifications held (e.g. ISO 9001, EN ISO 3834-2/3/4, EN 1090-1),
 - outsourced processes,
 - consulting firm (scope of consultation).
- estimated scope of certification:
 - classification level (CL),
 - type of activity (D - design, P - manufacturing, M - repair, S - purchase and supply),
 - types and specifications of manufactured products,
 - weld quality classes (CP),
 - class of testing (CT),
 - scope: material groups, welding processes, heat treatment, etc.,
 - personnel details: welding supervision personnel / representatives.

This data is used to check whether the required assessment and certification activities are possible, and to assess the size of the production facility in accordance with EN 15085-2 Annex C - in order to calculate the workload of the auditors. If this check is negative, the Customer will be informed. If the verification of the customer's application is positive, an offer is prepared based on it.

If the Applicant applies for certification while have a valid certificate issued by another certification body, a new certification audit is required. The applicant should inform the Certification Body about the reasons behind the exchange and provide the report from last audit prepared by the former certification body.

An application for the exchange of the certification body is approved only if at least 1 year has passed since the date of previous certification. Otherwise the Certification Body cannot perform the assessment process.

Fees for the activities associated with the certification process are calculated according to the real allocation of time necessary for performing the evaluation. The fees are determined on the basis of a calculation prepared by Certification Body.

Necessary information about certification according to EN 15085-2 is available at the Certification Body's web page including those certification conditions and related application template.

The precondition for commencing cooperation with the Certification Body is concluding a contract including those certification conditions.

Prior to the assessment, the conditions of execution are agreed with the Applicant.

Certification conditions EN 15085-2, Warunki certyfikacji EN 15085-2

The completeness of the application is reviewed to ensure that the information provided is sufficient for the evaluation and that the Certification Body has the necessary competencies and means to carry out the assessment.

4.2 Evaluation

The date of the audit is agreed with the Applicant and the scope of the certification presented in the audit plan. The evaluation shall be carried out in accordance with the audit plan.

The audit shall be carried out by conducting interviews, reviewing and analyzing documents, direct observation of operations on the Applicant's premises and by verification of the welded products quality. It shall assess the correctness of implementation and compliance with the applied certification level according to EN 15085-2.

In order to achieve full compliance with EN 15085-2, the Applicant shall meet the principal requirements described in standard EN 15085 series, in relation to the requested classification level (CL) and type of activity.

The results of the inspection are summarised in a report.

4.3 Review and certification decision

In accordance with Certification conditions BS I (MS-0034720).

4.4 Certificate, test mark

If the applicant meets all the specified requirements, the Certification Body makes a positive certification decision and issues a certificate with the corresponding validity range.

The certificate is issued for a period of three years from the date of issue, subject to satisfactory surveillance results.

The certificate is submitted to the Applicant together with an audit report.

In addition to the certificate, the Certification Body may also issue a certification mark (conformity mark).



4.5 Surveillance

Certification conditions EN 15085-2, Warunki certyfikacji EN 15085-2

The Certification Body shall supervise the issued certificate. Supervision is carried out by conducting supervision audits of the Applicant at annual intervals from the date of the first audit (within a time interval of +/- 3 months).

In the event of significant changes that may significantly affect the quality of production, the Applicant shall immediately submit a written statement ((e.g. on the application form) detailing the extent of the changes.

Significant changes that may affect certification, may be:

- change in the location of the production facility(s),
- changes in organizational structure,
- changes in welding supervision personnel,
- increase in the level of plant classification (CL),
- increase in the level of weld quality (CP),
- changes / modifications in welding technology,
- expansion of the range of welded materials (grades / thicknesses),
- change in the nature of production,
- changes in regulations and legislation.

The statement is subject to evaluation by the Certification Body as to whether a special audit is necessary. If the special audit is within 3 months of the next surveillance audit, the special audit can be combined with the upcoming surveillance audit.

4.6 Extension of certification

No additional comments with reference to the BS I Certification Conditions (MS-0034720).

4.7 Withdrawal, limitation, suspension of certification

The Certification Body may suspend, limit or revoke the validity of the certification in case of violation of these EN 15085-2 Certification Conditions, BSI Certification Conditions or in case of failure of the organization to meet the requirements.

The Certification Body shall give the company an opportunity to present its position before ruling on the restriction, suspension or cancellation of the certificate.

Once a decision is made, the company is informed by a "letter of termination"; the Certification Body may request the return of the certificate (which has become invalid).

The period of suspension of certification should not exceed one year. After this period, it is necessary to withdraw the certification. The procedure in the case of suspension of certification is determined individually by the Certification Body in a given situation.

4.8 Subcontracting

The Certification Body shall not subcontract certification activities within the program area.

Certification conditions EN 15085-2, Warunki certyfikacji EN 15085-2

4.9 Records / register of the test items certified

The Certification Body shall ensure the archiving of documentation from the process (for at least 2 certification cycles in the case of the surveillance and extension of the certification).

5. Roles and responsibilities

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

6. Local Specifications

N/A

7. Attachments

N/A

8. Related Documents

MS-0034720 *Certification conditions BS I*

9. External Reference Documents

Certification conditions EN 15085-2, Warunki certyfikacji EN 15085-2

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

EN ISO/IEC 17067 - Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes

DACW-01 - Accreditation of product certification bodies

*EN 15085-1+A1 - Railway applications – Welding of railway vehicles and components - Part 1
General*

EN 15085-2 - Railway applications. Welding of railway vehicles and components - Part 2 - Requirements for welding manufacturer

*EN 15085-3 - Railway applications – Welding of railway vehicles and components - Part 3
Design requirements*

*EN 15085-4 - Railway applications – Welding of railway vehicles and components - Part 4
Production requirements*

*EN 15085-5 - Railway applications – Welding of railway vehicles and components - Part 5
Inspection, testing and documentation*

*EN 15085-6 - Railway applications - Welding of railway vehicles and components - Part 6
Maintenance welding requirements*

PN-EN ISO 14731 Welding supervision -Tasks and responsibilities

Guideline of the European Committee for Welding of Railway Vehicles (ECWRV)