Testing and Certification Regulation

PZT GmbH

CE 1974

Notified Body according to Regulation (EU) 2016/425

Accredited by Deutsche Akkreditierungsselle (DAkkS) with authoritzation through Zentralstelle der Länder für Sicherheitstechnik (ZLS)
Scope: Regulation (EU) 2016/425 with ProdSG

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Contents

1 Area of Application

This Testing and Certification Regulation applies to all services which are defined by the NOTIFIED BODY PZT, within and according to the scope of Regulation (EU) 2016/425.

This includes

- the testing of products listed in Annex II 3.1 Head Protection as well as 3.5 Protection against the harmful effects of noise,
- the certification of products tested in accordance with Annexes II and V of the Regulation
- quality assurance for the final product Annexes VII and VIII of the Regulation
- awarding the GS-mark according to ProdSG,
- production plant audit within the frame of GS-mark award
- the storage of the technical documents for at least ten years following cessation of the production in question

This Testing and Certification Regulation of NOTIFIED BODY PZT GmbH, is subject to the General Terms and Conditions for the Supply of Services of PZT GmbH.

The testing and certification services are offered to all clients who want to introduce products onto the European market which are subject to a conformity assessment procedure in accordance with Regulation (EU) 2016/425.

2 NOTIFIED BODY

The NOTIFIED BODY PZT, is accredited for its range of tests within the legally regulated scope of Regulation (EU) 2016/425 and notified under EU ID. No. 1974.

3 Placing an Order

Testing, including certification, as well as product monitoring through PZT must be applied for in writing by submitting the “Antrag PSA (PPE Application)” application form to the NOTIFIED BODY. The relevant product documents must be submitted with the order in German or English if no other agreements have been made. If necessary, PZT can request translations from the client or order translations, all costs related to such translations will fall to the client.
By signing the application document (by an authorized representative of the applicant), the client accepts the Testing and Certification Regulation as contractual basis.
The application must be signed by an authorised representative of the applicant (client).
The application form must be filled completely and the following documents must be submitted together with the application form to the NOTIFIED BODY PZT:

Documents for certification:

- Data sheet, technical data
- Description and explanation of method of operation
- Operating manual
- Schematic drawing
- Component/Block diagram (if applicable)
- Parts list
- List of plastic materials used with information on flame-proofing
- Manufacturer Declaration(s)
- List of essential requirements and of harmonized standards
- Description of the control- and measurement devices used in manufacturing process
- A complete description of the PPE and of its intentional use;
- A risk assessment, describing the risks against which the PPE shall protect the user;
- A list of the essential health and safety requirements which are applicable to the PPE;
- The reference (s) of the harmonized standards referred to in Article 14 applied to the design and manufacture of the PPE (s). In the case of partially applied harmonized standards, the parts which have been applied are indicated in the documentation file;
- If harmonized standards have not been applied, or have been applied only in part, descriptions of the other technical specifications applied to meet the applicable basic health and safety requirements;
- The results of the design calculations, inspections and studies to verify the conformity of the PPE with the applicable basic health and safety requirements;

- Reports on the tests carried out to verify the conformity of the PPE with the applicable basic health and safety requirements and, where appropriate, to determine the relevant protection class;
- A description of the means by which the manufacturer, during the manufacture of the PPE, ensures its conformity with the design specifications;
- In the case of PPE, which are tailor-made for an individual user, all necessary instructions for the manufacture of such PPE on the basis of the approved basic model
- In the case of PSAs manufactured as standard, in which each individual item is adapted to an individual user, a description of the measures to be taken by the manufacturer during the assembly and manufacturing process to ensure that each specimen of the PPE conforms to the approved design type and fulfils the applicable basic health and safety requirements.

The documents should enable the device to be identified unambiguously and provide sufficient information for the necessary tests to be completed. If this is not the case, PZT is authorised to request further documents.
If the NOTIFIED BODY accepts the application, a contract is concluded for the client. The NOTIFIED BODY is entitled to reject orders. Reasons for the rejection are provided to the applicant.

Range of Service:
- Execution of all necessary measurements of the product according to the harmonized standards published in the Official Journal of the European Union
- Assessment of the technical documentation
- Conformity assessment activities
- Issuance of the EC-Type Examination Certificate and, if requested, the GS-mark permission (it is not possible to issue GS certifications for PPA Category III products)
- Where applicable, auditing of manufactured goods or production plants
- Storing of the documents for at least five years after the end of the period of validity of the Type Examination Certificate for the product concerned.

4 Subcontracts

In exceptional cases, the NOTIFIED BODY is authorised to charge other bodies to complete the testing or partial testing of products. Costs accrued through commissioning or contribution by other bodies will be charged to the client separately. Commissioning or contribution by other bodies requires advance agreement with the client.

5 Obligations to Secrecy

PZT is obliged to treat any information gathered within the scope of fulfilling the order as confidential and to maintain secrecy.

6 Testing a Product

The model is tested in the test laboratory of the NOTIFIED BODY PZT, in Wilhelmshaven. The tests are based on the requirements stipulated in Regulation (EU 2016/425 with the corresponding harmonized standards, implementing the applicable measuring procedures. Resolutions (Recommendation for Use) determined by national and European working committees also apply. For granting the GS-mark the ZEK Decisions are also applicable.
To complete the tests, operational type samples must be provided to the NOTIFIED BODY free of charge in the numbers agreed as well as any tools, consumables and spare parts. Due to the test conditions, test samples could be soiled, worn or damaged. There are no rights to claims for compensation from PZT following this type of impairment or damage.
The client must ensure the availability of a contact person who can provide any necessary information on the test samples following a request from the NOTIFIED BODY.
The test laboratory produces a test report on the type sample in English if nothing else has been agreed on. Test reports for the issuance of the GS mark are written in German. At the request of the monitoring authorities, test reports can also be translated into the corresponding country languages. The client receives a copy of the test report as a PDF-file (and a paper copy upon request) on completion of the certification process.
On completion of the testing and certification process, the NOTIFIED BODY may return each test sample in its respective condition following testing (e.g. possibly defective) to the client at the client's cost, e.g. as "freight collect".
In the event of a product test with negative results for which a re-test shall be performed at short notice, free storage of the type samples is assured for a maximum period of three months. After this period, or in the case of a cancellation of the conformity assessment activities, the test samples will be returned to the client at his expense.
If the client does not pick up the type samples despite a written notification to do so, or refuses receipt, following a period of one month storage at the expense of the client, the test samples will be disposed of.
If the test is concluded with a certification, EC type-examination certificate, the NOTIFIED BODY defines whether the test samples must be kept as a storage sample in the PZT stores or returned to the client for storage having been identified and, if necessary, sealed. Assurance must be obtained from the certificate owner that the storage sample can be made available at any time for control purposes. If certification is awarded but, due to its constructional design, the sample cannot be stored by either PZT or client, or storage of the sample is dispensed with for other reasons, a detailed documentation of the sample must be produced at the expense of the client so that all the test-related aspects can be inferred from the documentation.
Samples or documentation handed over to the client must be made available to PZT at short notice and free of charge on request. If, following request, the client is not in a position to provide storage samples and/or documentation, all related rights to liability claims in respect of property and assets of the client from PZT are annulled for the respective test and certification.
The basic period of storage of samples, the documentation and the Certificates of Conformity shall be five years from the end of the period of validity of the Type Examination Certificate. Any costs for storage and later disposal by PZT will be charged to the client.
If test samples or storage samples are lost in the laboratory or stores, or damaged as the result of burglary, theft, water, fire or transport, PZT is only liable in cases where there is evidence of gross negligence.

7 Certification of a Product

After the test report compiled by the test laboratory and any necessary technical documents have been submitted, the test result together with the documents are assessed. In the case of a positive assessment, a report is produced and an EC type-examination certificate is issued in German and English. A type examination certificate according to Regulation (EU) 2016/425 is only valid if a contract for supervised product checks, Annex VII, Module C2 or for supervision of the production process and an assessment of the quality assurance system, Annex VIII, Module D has been concluded. The certification is valid for the running production, if the product is in compliance with the examined type. The validity of the Type Examination Certificate is a maximum of five years.
The client is notified of a negative assessment and the main reasons are defined.

Once the validity period of maximum five years expires (at least 12 no later than 6 months before expiry the manufacturer declares in a request whether the production still exists and the product is still manufactured in unchanged form. If this is the case, the PPE regulation Annex V, 7.6 is followed. It is confirmed to the manufacturer that no changes have been made to the approved sample and the state of the art, and the Type Examination Certificate of the product will be issued for a further maximum of five years.

The NOTIFIED BODY must be informed immediately of any planned modifications to the construction and production of products as compared to the samples tested due a change in the state of the art and which could be relevant in respect of the tests completed regarding the acoustic and physical parameters. The certificate owner must also inform the NOTIFIED BODY immediately with regard to changes to the company (changes to the name, legal, economic or organisational status), assignment of production plants to another company / company owner, of the organisation and the management (e.g. nomination of key positions, decision-making processes or technical staff), changes to the product or production process and substantial changes to the quality management system.
The NOTIFIED BODY will decide whether the certificate will continue to be valid, involving a review for which charges will be made if necessary, and will produce a corresponding supplement to the existing certificate as necessary.

8 Quality Assurance for the Final Product

For the period of validity of the contract on product monitoring the client is obliged:

- to monitor the production of the certified products in order to secure that they are in compliance with the examined types,
- to enable the NOTIFIED BODY at any time, to take products from the running production and to conduct periodical checks of production through PZT,
- to announce to and have checked by the NOTIFIED BODY any product changes, caused by further development or change of components,
- to notify the NOTIFIED BODY in a timely manner of the intended transfer of production or any change of the company,
- if the certificate owner is not identical with the manufacturer of the certified products, to make an agreement with the manufacturer on the applicable conditions during production, which include the consent to necessary control measurements,
- to accept that PZT is allowed to pass information on the certified product, received through legal or official obligatory registration, and that on request of an EU-member state or an Accreditation Authority, PZT is authorized to disclose information and documents regarding the contract with the client as well as the contractual object. This comprises especially information on the granting and withdrawing certificates, which are directly or indirectly related to the tested products.
- PZT reserves the right to debit the cost incurred for identifying and clarifying such incidents to the client's account.

9 Product Inspection, Module C2, (Regulation Annex VII)

Category III products are subject to product inspection or quality assurance related to the production process. According to contractual agreement, PZT will ask the certificate holder to release information as to where products from the latest production batch can be removed. The client grants PZT free admission to the manufacturing facility and stock, in order to remove test samples for inspection. The product will be compared with the certified type, and inspections will be carried out. If deviations with respect to the certified type or defects are noted, the client is obliged to find out and trace back the cause. Only upon successful elimination of the shortcoming may the product be released for sale. PZT reserves the right to request from the client repair/improvement of products which are already on the market. If the client fails to meet these requirements, PZT reserves the right, to suspend or withdraw the certification.
All costs related to product inspection are calculated according to time and effort involved and are to be paid by the client.

10 Inspection of the Manufacturing Facility, Module D (Regulation Annex VIII)

For the quality assurance related to the production process and prior to the granting of the GS-mark to the client, PZT performs, based on ProdSG, Regulation (EU) 2015/425 and ZEK-decisions, an initial factory inspection. In the following annual factory inspection samples will be taken for product surveillance. For these purposes PZT shall be granted access to the manufacturing plants; where appropriate, the participation in surveillances shall be made possible.
The client will inform PZT immediately of relocation of a manufacturing plant or the transfer of a manufacturing plant to another company/company owner. If, due to a transfer of manufacturing plant, an inspection through PZT shall be necessary, the client shall make this possible.
All related costs for carrying out the factory inspections and the product surveillance shall be invoiced to the client.

11 Use and Publication of Test Reports and Certificates

Test reports and certificates may only be used in full.
Publication or copying for advertising purposes requires written approval from PZT in all cases.
Upon receipt of the report or the certificate or the EU Type Examination Certificate, the applicant is entitled and obliged to affix the corresponding "CE" conformity marking in accordance with Regulation (EU) 2016/425, Article 17, to the products conforming to the tested type. Category II products are only to be marked with the CE mark, category III products with the CE mark and the EU identification number of the Notified Body.
If in addition to the EC-Type Examination also the GS-mark has been granted, the GS-mark can be affixed on the product for the period of validity. The respective PZT provisions have to be implemented.
If the certification documentation is transferred to third-parties, they have to be copied completely. Where the product certification is mentioned in communication media such as advertising documents or brochures or any other promotional material, the PZT provisions and the requirements to the conformity mark have to be fulfilled.
The product certification shall by no means be used to mar the reputation of the Notified Body. No comments shall be made on product certification, which could be considered by the Notified Body as deceptive or unsubstantial.
The NOTIFIED BODY is authorised to publish the issue of the certificate and inform the member state, provided the NOTIFIED BODY is legally obliged to do so. Agreement must be obtained from the certificate owner prior to any other publication of certificates.

12 Obligation of the Client for Documentation of Complaints on Certified Products

In case of complaints on certified products the client has to provide detailed records, which explain appropriate actions. On request, these shall be submitted for inspection to the certifying body.

13 Validity of Certificates

The validity of the certificates applies according to the definitions in Regulation (EU) 2016/425.
A certificate becomes invalid when:

- the period of validity has expired after five years and has not been extended,
- the certificate owner terminates the production or sale of the product,
- the certificate owner applies for a withdrawal of the certificate,
- the certificate owner no longer fulfils the obligations arising from this Testing and Certification Regulation,
- it becomes apparent that the certificate owner or his authorised representative has deceived or attempted to deceive the testing and certification body or their representatives,
- the certification mark or certificate has been used incorrectly or when legal provisions were not maintained as the product was marketed,
- the certificate is used for products which do not conform to the tested sample,
- defects are subsequently found in the products which were not detected during the tests and were not cleared within the deadlines defined, despite a written request from the NOTIFIED BODY, or other facts have become apparent which would have prevented the award of a certificate,
- considerable deficiencies in the quality assurance of the product appear,
- the legal basis for certification of a product no longer exists.

Depending on the seriousness, the certificate may be restricted or suspended for a short time until the revealed shortcomings are eliminated.

The NOTIFIED BODY may insist on the return of the certification documents. The client commits to stop all advertising efforts in connection with this certification, unless the certification is transferred to another NOTIFIED BODY.

14 Charges

Expenses accrued for the activities completed by the NOTIFIED BODY in accordance with this Testing and Certification Regulation will be charged to the client as defined in the contractual agreement. The basis for this is the valid fee schedule of the NOTIFIED BODY.

15 Arbitration Process

In the case of disputes resulting from the activities completed by the NOTIFIED BODY, each contractual partner can contact the management of PZT GmbH. Information on the dispute and appeal procedures can be downloaded from the PZT website. The PZT management will then attempt to clear the dispute within the terms of an arbitration tribunal together with the client and the measurement technology management and certifying body.

16 Validity

This Testing and Certification Regulation applies to testing and certification orders concluded with the NOTIFIED BODY PZT GmbH from April 21st, 2018.

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