Regulation of Test Approval and Certification

General Conditions and Procedure Guideline for the Certification of explosion-protected Products according to Directive 2014/34/EU or the IECEx Scheme of Certification body of TÜV Rheinland Industrie Service GmbH

Content

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0. Introductory

The Certification body for explosion-protected products according to Directive 2014/34/EU of TÜV Rheinland Industrie Service GmbH (named below as certification body), member of IECEx Scheme offers interested companies its services among others for the certification of explosion-protected products. It is a notified body in the sense of EC Directive (official number 0035) and certification body (CB) and test laboratory (ExTL) within the IECEx Scheme.

The IECEx Program is an International Certification Scheme covering products that meets the requirements of International Standards, e.g. IEC Standards (see further under http://www.iecex.com/about.htm).

The obligation and guarantee of independence and neutrality are given by both:TÜV certification standard and the rules of IECEx. Due to the existing company organisation structure and organisation of procedure of TÜV resp. IECEx the specified criteria of DIN EN ISO/IEC 17065 are being fulfilled. The organisation and the sequence of the certification procedures are being documented in the relevant Quality Management documents.

1. Scope and Terms

The “Regulation of Test Approval and Certification” regulates the examination and certification of explosion-protected products on the basis of Directive 2014/34/EU as well as on rules of IECEx. Explosion-protected products in the sense of this Regulation of Test Approval and Certification are all products, which are intended for use in potentially explosive atmosphere.

The EU Type Examination is a conformity assessment procedure carried out by a notified body for Explosion-Protection according to Annex III of EC Directive 2014/34/EU, the conformity of which will be confirmed by an "EU Type Examination Certificate".

The Conformity Certificate will be issued by a notified body if it should be found out that in the conformity examination the product fulfils the requirements of the Directive according to Annex V or individual test according to Annex IX of EC Directive 2014/34/EU.

The Conformity to type notification will be issued by a notified body if it should be found out that in the conformity assessment the product fulfils the requirements of the Directive according to Annex VI.

The Type Examination is a conformity assessment procedure in the non-regulated market carried out by the certification body for explosion-protected products following Annex III of EC Directive 2014/34/EU for equipment and components, for which the manufacturer must perform the conformity assessment acc. to Annex VIII of EU Directive 2014/34/EU only. The "Type Examination Certificate" confirms the conformity of the type with the requirements of the directive 2014/34/EU.

Declaration of Conformity is a procedure in which the manufacturer confirms that his product fulfils the appropriate EU Directives.

The IECEx Certificate of Conformity (COC) is a document issued under the rules of IECEx indicating that adequate confidence is provided that a duly identified product is in conformity with a specified standard.The certificate can relate to ex apparatus, components or an ex system.

The IECEx Test Report (ExTR) is a document issued by an ExTL that includes a documented record of the obtained test and assessment results for endorsement by an ExCB, associated with the issuing ExTL, demonstrating that the examined product type is in conformity with specified standards.

The IECEx Quality Assessment Report (QAR) is a document that presents the results of an on-site assessment of a manufacturer`s quality control system by an ExCB, to the requirements of the IECEx Scheme.

Placing on the market: the time at which the manufacturer puts the product at its user's disposal for the first time.

2. Test Approval and Certification Procedures

2.1 Conformity Assessment Procedures

It will be found out in the conformity assessment procedure whether a product fulfils the requirements of Directive 2014/34/EU resp. the relevant IEC standards to the requirements of the IECEx Scheme.

2.2 Prerequisites of Order

2.2.1 For the initiation of the conformity assessment procedures, the manufacturer (named below as client) applies to the certification body of TÜV Rheinland Industrie Service in writing for the test approval and certification of explosion-protected product which will be placed on the market under the consideration of the required information and documents which are mentioned in the related Annex of the Directive respective in the IECEx Scheme acc. to the document OD 017. The client declares with his order, that he is holder of rights concerning concept, design and manufacturing of the ordered product to be tested, and no rights of third parties are violated in particular no trademark rights, utility patents and/or patent rights. The certification body is not bounded to prove the trueness.
In case the product, which the client wants to be tested, is proven to be undisputed or verifiable a plagiarism, the certification body is authorised to abort the testing and to charge the originated work. Evidence for plagiarism must be provided by a legal ultimate court decision. Furthermore notice is given that a monetary penalty acc. to item 3.15 of this Regulation of Test Approval and Certification is possible.

2.2.2 For the first placing of an order to the certification body with the aim of a certification or a testing, it concludes with the client a "Contract concerning Test Approval and Certification". This "Regulation of Test Approval and Certification" is an integral part of this contract. By signing the contract both parties will agree to this regulation of test approval and certification. Attached to the application in the regulated market is a written declaration of the client that no other certification body (notified body) is being appointed to carry out the same procedures. This declaration is not needed in case of a type examination.

2.2.3 The test approval and certification orders will be processed in the series of sequence upon receipt of the required documents and test samples.

2.2.4 Technical documents

2.2.4.1 Product-testing
The handing over of the technical documents in double engrossment, as drawings, part lists etc. in accordance to the list stated below shall be forwarded to the certification body possibly together with the order. The technical documentation must contain the necessary safety related criteria for the assessment of the product in order to confirm the compliance with the requirements of the directive or the IECEx-Scheme. It shall, to the necessary extent for such assessment, cover the design, manufacture, function and operation of the product and shall contain:

- a general type-description
- design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for understanding of the said drawings and layouts and the operation of the product;

- results of design calculations made, preliminary tests, test reports, examinations carried out, etc. as applicable with respect to the applied standards;
- for Directive 2014/34/EU only:
  - List of the standards referred to in Article 5, applied in full or part. Listing of the clauses of standards which have not been applied.
  - Description of the solution adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied.
- for IECEx-Scheme:
  - a list of the standards, which are applied in full and a list of national deviations which the product has to fulfil in addition
- Declaration of conformity and/or CoC for ATEX and/or IECEx of used components
- Declaration of the manufacturer that the product for the not ex-relevant parts is in conformity with all relevant European Directives and/or standards
- Installation-/ operation- / maintenance- manual etc. with all statements to the scope of application and normal use inclusive the description of remaining hazards and the special conditions of safe use.
- Test-reports
- For machinery and other non electrical equipment the following is valid:
- Declaration of conformity acc. to the machinery directive with information to the scope of application.
- Ignition hazard analysis acc. to EN 1127 and/or EN/IEC 80079 series.
- Relevant calculations of safety relevant parts and characteristics
- Documentation of external products, e.g. motors, switches etc. including the statements to the conformity with the directive 2014/34/EU or with a CoC according to the IECEx Scheme 02.

The documentation shall be minimized but must contain the necessary safety characteristics for the assessment. The ex-relevant details in the documentation must be accentuated by coloured or other marker or by detailed summary and therefore clearly identifiable. A non-observance of this requirement leads as a rule to a higher assessment effort, which has not been calculated in the offer price. For the preparation of the documentation the attached operational document OD17 may be used as a guideline. Attention must be paid to the annexes to this regulation of test approval and certification.

One or more test samples have to be delivered according to the request of the certification body. If necessary, special conditions for the preparation of the test sample will be made known.

2.2.4.2 Examination of the conformity to type acc. to annex VI

Examination and assessment of the documentation, as e.g. procedural requirements, work instructions, marking, manufacturing, testing, test equipment supervision, control of incorrect products and handling of products as well as design drawings, calculations and type examination certificates, concerning plausibility and conformity with the requirements of the directive.

2.3 Examinations/audits

2.3.1 The tests shall be carried out in a certain test laboratory which is decided by the certification body or at a suitable external test side or test stand or at an installation place which is named by the client.
Partial tests can be performed by the following subcontracting laboratories:
TÜV Rheinland TRLP, Laboratory Mitutoyo or
TÜV Rheinland Laboratories in different countries, all authorized by German Authority ZLS and/or by IECEx Scheme 02..
All the key tests for type of protection flameproof “d” will be done in the own Laboratory of TÜV Industrie Service GmbH in Cologne.

2.3.2 The delivered test sample shall, after the certificate is being granted or otherwise signed due to the kind of agreement, be scrapped, be kept by the certification body, or given back to the client

for storage or his disposal. The certification body decides if a secure storage of a storage sample over the period of storage of the technical documentation is necessary. In this case the test sample will be taken into custody by the certification body or signed and given to the client.
In all cases the securing of the test samples by means of documentation shall be made and, as far as necessary, a temporary securing of the samples at the operation place of the tested product shall be agreed.

Regarding the keeping of test samples, the examination of which does not entitle to a certificate, agreements will have to be met with the client from case to case. The certification body is not liable for damages to the test samples caused by the examination as well as by burglary, theft, fire or water. It has to take care that the samples will be treated or handled in the same way as its own property or business (§690 BGB, German right).

Costs in connection with transportation, storage or scrapping of the test samples will be borne by the client.

2.3.3 The results of the tests/the audits shall be documented in a written confidential test report/ audit report, which will be given to the client. If there are no claims arising from the test procedure, the test report will then be sent to the certification body together with the relevant technical documents.

2.4 Performance of site inspection of the place of manufacturing in connection with the module conformity to type acc. to annex VI.

Inspection of manufactured products (acc to conformity to the approved type) and the production techniques (to guarantee an equal quality) including exemplary routine tests.

3. Granting and Utilisation of Certificates

3.1 The certification body checks regarding the completeness and technical correctness the results of conformity examination.

3.1.1 A certificate according to the directive 2014/34/EU will only then be granted if the tests do not result in deviations to the Directives which were taken into consideration and safety-related faults. Solutions which are deviated from standards have to be described, tested and accepted in hazardous analysis and are not allowed to show any safety-related faults in the implementation.

3.1.2 An IECEx Certificate of Conformity (CoC) will only then be grated if the tests do not result in deviations to the standards which were taken into consideration.

3.2 The following certificates respective reports can be granted in dependency on conformity assessment procedure:

3.2.1 Certificates regulated by the directive 2014/34/EU
- EU Type Examination Certificate
- Conformity Certificate (according to product verification or unit verification)
- Notification concerning the Conformity to Type

3.2.2 Certificates not regulated by law

3.2.2.1 Certificates not regulated according the requirements of the directive 2014/34/EU
- Type Examination Certificate

3.2.2.2 Certificates and reports according the IECEx Scheme
- IECEx Certificate of Conformity (CoC)
- IECEx Quality Assessment Report (QAR)
- IECEx Test Report (ExTR)

3.3 The right to use the certificate by the client applies only to the complete product as being tested and mentioned in the certificate and for which the owner of the certificate holds all rights.
The product must only be taken apart so far as it is necessary for the transportation. The conditions are laid down in the instruction or operation sheets.

3.4 The client is allowed to make use of the CE conformity marking according to the regulation of the Directive after the granting of a certificate or a combination of certificates and notifications which are regulated under the directive.

3.5 The certification body can demand a contract penalty in case violations can be found against the "Regulation of Test Approval and Certification", in particular in case of illegal use of a mark or a certificate. The certification body reserves his right to enforce legally additional recourse claims against the client or the abusive user of marks. Shall the contract be cancelled by the certification body due to unlawful use, the adduced and agreed services as agreed in the order, has to be paid. In addition a payment shall be made according to the contract arrangements for the not yet generated and cancelled services.
An illegal utilisation exists as well if the product, before the applied certificate is being granted, with the mark of the certification body is being placed on the market and so that inadmissible advertisement is being conducted.

3.6 A certificate can only be transferred to a third person by the certification body with the allowance of the client. A contract for this purpose has to be concluded beforehand according to the request of application. The identification number of the product has to be changed in order that the origin of the product can be differentiated.

3.7 Certificates can be granted for a unlimited or limited period and under restrictions or obligations. The valid time of EU Type Examination Certificates is not limited.

3.8 A certificate becomes invalid if
- the client abandons the certificate,
- the "Contract concerning Test Approval and Certification " is being terminated by one of the contract parties in accordance with the notice of termination,
- the client gets into bankruptcy or an application of bankruptcy disclosure directed against him is being rejected because of lack of estate,
- the requirements, which are the basic standards of the certificate, were amended or other requirements, e.g. because of the changed utilisation, have to be applied.

3.9 A certificate can be withdrawn by the certification body if
- hidden faults of the product should be found out afterwards,
- a review of the indicated product with a CE mark and the reference number of the certified body shows serious faults,
- misleading or other inadmissible advertisement in relation to the certificate is being conducted,
- the client refuses or does not facilitate the production surveillance and does not let the surveillance carry out despite of written request by the certification body,
- based on the facts which were not be recognised at the time of granting of certificate,
- the certificate or confirmation should not have been issued or the formulated conditions were not being fulfilled in an appropriated or stipulated period.
- a egal ultimate court decision for the legal proof of plagiarism exists

3.10 The certification body can make known to the public the invalidity or the withdrawal of certificates according to its own choice.

3.11 The certification body is authorised to inform the supervisory authorities, the accreditation bodies, the notified and other bodies and the registration authorities about the granting, invalidity or withdrawal of certificates.

3.12 The certification body is not liable for the disadvantages which arise to the client because of non-granting, invalidity or withdrawal of a certificate.

3.13 Is a certificate being withdrawn, the client is therefore obligated to remove the related CE type mark from all the products which can be reached by him and to make possible a relevant control by the certification body or a body appointed by the certification body. The arising expenses will be borne by the client.

3.14 After the expiry of valid period of a certificate, the existing stock at this time can be allowed to place on the market for an appropriate period, however, not longer than two years.
Stocks of products, which carry the reference number of the certification body, have to be made known to the certification body on demand.
For the limited period of placing on the market, the contractual resolutions between the parties remain valid.
A marketing permission will not be given if the certificate is being declared as invalid.

3.15 A QAR can be suspended or withdrawn by the certification body
In this case the certification follows the Requirements and Guidelines for the Suspension, Cancellation and Reinstatement of Certificates of Conformity and QAR according to IECEx OD 209

3.16 The certification body is entitled to claim a contract penalty of 25.000 Euro in the case that a test job has to be aborted due to a verifiable plagiarism. (see 2.2.1)

4. Inspection of the Production and Installation

4.1 For the guarantee of the same constant product quality, the certification body can carry out regular inspections of the production plant and test equipment at the expenses of the certificate owner as requested in the EC-Directive, Standard or in case of IECEx as required in the IECEx Scheme. A contractual inter-connection to the regular inspection in respect of quality safety system in the framework of a TÜV-certificate for quality safety systems according to Ex-Protection Directive or in the framework of IECEx Scheme (QAR) is possible and can be separately agreed.

4.2 Above that, the certification body can inspect at any time without prior notice the production and operation factories as well as the storerooms which are mentioned on the certificate (in the case that the owners of certificate are in foreign countries, the storerooms of their authorised representatives and their branches will be inspected; in the case that the owners are importer, their storerooms will be inspected) and take the products, for which a certificate is being given, free of charge for the purposes of reviewing.

4.3 The certification body can take the products, which carry its mark, from the production factories within the framework of operation for reviewing or check at the installation place regarding the appropriate determinate utilisation.

4.4 The owner of the certificate obtains a written report about the result of the review.

In case faults are to be found in reviewing and it is necessary to have an additional inspection, the arising costs of which have to be borne by the owner of TÜV-certificate.

5. Obligations of Certification Body

5.1 The TÜV Certification Organisation as well as the IECEx Organisation and the members of the certification bodies commit themselves to handle all the information which are made accessible to them about the business of the client confidentially and analyse only for the agreed purpose. The accessible document shall not be given to a third person. Herewith excluded is a thorough report to the court of arbitration in case of disputes. The client can release the pledge of confidentiality from the certification body because of specified reasons.

5.2 The liability of the certification body to the client or third person is only so far provided as laid down by the law in the cases of intention or major negligence. Further claims are excluded.

5.3 The head of the certification body is obligated within his possibility to pay attention to the correct description of certification in advertising measures done by the client.

6. Contribution of Clients

6.1 The client takes all necessary measures to ensure that the production or the manufacturing process fulfils the requirements of the directive 2014/34/EU and / or IECEx Scheme and that the conformity with the technical documents is assured.

6.2 The client is obligated to keep under surveillance the production of the certified products corresponding to the certified test sample continuously.
The carried-out examination with the result of granting of certificate does not release the client from his lawful product liability.

6.3 The client informs the certification body immediately the amendments made by him to the product compared to the certified version of test sample or intended or alternatively implemented changes to the product. The further validity of the granted certificates depends on the proof given by the client about the maintenance of the Directive's requirements or on an additional examination. Under the regulations of the directive 2014/34/EU it is possible to issue supplements to the original certificate. Under the regulation of the IECEx Scheme an up-issue of the certificate has to be done if the product has been changed.

6.4 The client informs the certification body the intended moving of inspected production factories in time or the intended transfer of his company to another company or another owner.

6.5 The client is obligated to advise the certification body damages and accidents caused by the tested products.

6.6 The client has to register and put into archives all complaints relating to his certified product. Upon request of the certification body, he has to put the documents at disposal free of charge and inform about the measures taken by him to eliminate the existing justified complaints.

6.7 The client is obligated to stop immediately the production of products, which carry a CE mark, should serious safety faults be found afterwards and to take suitable measures to minimise the damages in market. In each case, he has to stop the placing on the market of the indicated products directly and inform the certification body.

6.8 The client is obligated to put certificates, confirmations, documents or proved samples which were delivered to him for storage into archives for a period of ten years after the turning down of production of products or for a period of ten years after placing on the market of products and upon demand of the certification body to put them at disposal free of charge. Above all that, requirements from other legal works will remain unaffected.

6.9 The client is allowed to forward or to make public the test reports and certificates only in their completed wordings.

6.10 The client has the possibility to proper use of IECEx logo in accordance with instructions provided as published in IECEx 01B.

7. Objection Procedures

7.1 The client can submit objection or complaint to the certification body about the unsatisfactory decision of the certification body against him in the framework of the carried-out certification procedures. The certification body has then to give a detailed reason for his decision to the appellant.

7.2 Should the given reason of the certification body for the appellant be not acceptable, so the way to submit the complaint to the leading committee of the certification body is open for him.
The leading committee has to meet a definite conclusion of resolution.

7.3 Should the given reason or conclusion of resolution of the leading committee for the appellant be not acceptable, the applicants have their right of appeal to IEC if they are not satisfied with the outcome of the ExCB appeal process. The process is to submit the complaint to IEC via IECEx in accordance with CA 01 and IECEx 01-S

8. Inception and Modification

8.1 The Regulation of Test Approval and Certification becomes effective on15-01-2022.

8.2 It is valid basically for all certificates which are being granted in the period of validity.

8.3 Modifications in the future to the “Regulation of Test Approval and Certification” can be applied to the existing certificates in writing upon agreement with the owners.