



Technical Guide

Ex PRODUCT CERTIFICATION SCHEME

Directive 2014/34/EU

IECEx Scheme

1. INTRODUCTION

The purpose of this Guide is to clarify all details relating to the conformity assessment procedure of equipment, components and systems intended for use in explosive atmospheres of gasses, vapours, mists and dusts (Ex products). The procedure described in this Guide is applicable to products conformity assessment based on Annex III and Annex IX, and to deposition of documentation according to Annex VIII of the European Directive 2014/34/EU (the Directive). The procedure is also applied to products conformity assessment according to the requirements of the IECEx Scheme.

This Guide also provides an overview of the conformity assessment procedure of category 3 equipment and category 2 non-electrical equipment (excluding motors with internal combustion) wherever such is requested by the manufacturer.

Conformity to requirements specified in The Directive is based on harmonized European standards and to assess conformity with the requirements of the IECEx Scheme, international IEC/ISO standards are used.

This Guide does not contain details of the assessment of production quality systems and products according to Annexes IV and VII, which are described in the Certification of manufacturer's quality system (TU-PR-ATEX).

2. APPLICATION FOR CONFORMITY ASSESSMENT

To initiate the conformity assessment procedure, the manufacturer or manufacturer's representative must submit request with draft certification documentation and Risk assessment documentation in case of certification according to Directive 2014/34/EU (see ExNB_CS-016_Risk assessment documentation). Applicant can use Fiditas application form (available on Fiditas website). Upon receipt of the request, documentation will be evaluated and if found suitable, Fiditas will generate and send the offer to the Client together with the Agreement and manufacturer's statement. If the offer is accepted, the manufacturer submits an order and a copy of the Agreement and manufacturer's statement signed by the manufacturer and delivers certification documentation in accordance with Annex III, item 3, and Annex IX, item 3 of the Directive or according to the requirements of the IECEx Scheme (IECEx OD-017). Fiditas will provide written confirmation of receipt of the order and will initiate the procedure.

The preparation of the Risk assessment documentation is described in the Guide to the Application of the Directive 2014/34/EU, para. § 142 Principles of integrated explosion safety. Risk assessment for ATEX products). For electrical Ex equipment, Fiditas does not assess the delivered Risk assessment documentation, but only deposits it with the certification dossier in accordance with ExNB_CS-016.

3. TYPE EXAMINATION PROCEDURE

Type examination conformity assessment is performed according to Annex III of the Directive or per requirements of the IECEx system (IECEx 02 – Equipment certification – IECEx certificate of conformity). If the assessment results are satisfactory, Fiditas will issue EU-Type Examination Certificate to the Client with the following mark form „FIDI yy ATEX nnnn“ followed by ‘X’ or ‘U’ where applicable or IECEx certificate of conformity (IECEx CoC) marked IECEx FIDI gg.xxxx. The certificate is issued without time limit of certificate

validity. Such certificate confirms the conformity of Ex-protection of the representative sample(s) and certification documentation with the Directive and relevant standards.

Procedure for the issuing EU-Type Examination Certificate

The certification procedure is carried out in three phases:

- a) Evaluation of certification documentation
- b) Type testing of samples
- c) Evaluation of test results and issuing of certificate

Fiditas evaluates test results and the certification documentation submitted and if results of the assessment are satisfactory issues the EU-Type Examination Certificate to the Client.

If the assessment of test results and certification documentation identifies non-conformities with requirements, Fiditas will notify the Client, stating the reasons for refusal to issue certificate.

With receipt of this certificate the manufacturer does not acquire the right to manufacture and place equipment on the market, but must implement one of the 2014/24/EU Annexes relating to Production or Product Quality Assurance (Annexes IV and VII), Product Verification (Annex V) or Conformity to Type (Annex V).

Responsibility for conformity of Ex products with Essential Health and Safety Requirements (EHSR) of the Directive lies with the manufacturer. In case where standards listed in EU TEC are no more harmonized with the Directive, manufacturer shall take the necessary action (see ExNBG/10/397/CS) even if EU TEC has been issued without validity date.

Procedure for issuing an IECEx Certificate of Conformity

The certification procedure is performed in 5 phases:

- a) Evaluation of certification documentation
- b) Type testing of the product
- c) Test assessment and issue of IECEx test report (ExTR)
- d) Quality assurance assessment of production
- e) Preparation and issue of certificate (IECEx CoC)

4. UNIT VERIFICATION CERTIFICATION

Unit verification procedure is performed according to Annex IX of the Directive or per the requirements of the IECEx Scheme (IECEx 02 – Equipment certification – IECEx Unit verification certificate. If overall results of the evaluation are satisfactory, Fiditas will issue the Certificate of Conformity to the Client, marked “FIDI yy ATEX Pxxx” followed by X or U where applicable or IECEx Certificate of Conformity – Unit Verification (IECEx CoC) marked IECEx FIDI gg.xxxx. The certificate is issued without a time limit and confirms the current state of Ex-protection of the product.

The ATEX certification procedure is carried out in three phases:

- a) Evaluation of certification documentation
- b) Testing of product
- c) Evaluation of test results and issuing of certificate

Fiditas evaluates test results and the certification documentation submitted, and if results of the assessment are satisfactory issues the Certificate of Conformity to the Client.

If the assessment of test results and certification documentation identifies non-conformities with requirements, Fiditas will notify the Client, stating the reasons for refusal to issue certificate.

With receipt of this certificate the manufacturer acquires the right to place products on the market, issue a declaration of conformity and place Fiditas's number (2829) along with the marking CE.

Procedure for issuing an IECEx Certificate of Conformity – Unit verification

The certification procedure is performed in four phases:

- a) Evaluation of certification documentation
- b) Product testing
- c) Test assessment and issue of IECEx test report (ExTR)
- d) Preparation and issue of certificate (IECEx CoC)

5. VOLUNTARY CERTIFICATION (ATEX)

The manufacturer or manufacturer's representative may request certification from Fiditas for equipment for which the Directive does not mandate the issuing of a certificate from a recognized third party (ATEX Notified Body). This applies to group II category 3 equipment as well as for group II category 2 non-electrical equipment (excluding motors with internal combustion).

Fiditas will perform the product type examination procedure as described in item 3 or unit verification procedure as described in item 4 of this Guide. In the event of satisfactory results of the evaluation of documentation and test results, Fiditas will issue a Type Examination Certificate or Certificate of Conformity.

Issuance of voluntary Type Examination Certificate or Certificate of Conformity for group II category 3 equipment as well as for group II category 2 non-electrical equipment (excluding motors with internal combustion) doesn't exclude obligation of manufacturer to deposit the technical file (see item 6 of this Guide) at Notified Body as required by Directive 2014/34/EU. If manufacturer order voluntary certification from Fiditas, Confirmation on deposition of documentation will be issued to manufacturer with voluntary certificate.

6. DEPOSITION OF DOCUMENTATION

This procedure is applied to the deposition (storage) of documentation for group II category 2 non-electrical equipment (excluding motors with internal combustion), for the purpose of marking with the symbol of conformity, in accordance with Annex VIII of the Directive.

For group II category 2 non-electrical equipment, the supplier must, for the purpose of CE marking, perform the procedure that refers to internal control of production as per Annex VIII of the Directive and deposit the documentation with the Notified body.

In this case Fiditas does not check/endorse the technical documentation. The manufacturer shall provide FIDITAS with the technical documentation in a sealed envelope/package with the following information defined:

- Name and type / model of the product
- Manufacturer's name

- Manufacturer's address
- Technical documentation designation (eg. number, issue, etc.)
- Date of technical documentation.

In accordance with the Guide to the application of Directive 2014/34/EU, edition 5 of April 2024, § 113 Retention of technical documentation, the manufacturer must submit the content of the technical documentation so that the Notified Body can check its completeness (see also Annex VIII of the Directive). The contents (index) can be indicated on the envelope/package or delivered on a separate letter.

Fiditas deposits technical documentation for a minimum of ten years from the date the confirmation is issued. It is the responsibility of the manufacturer to assure the deposition of technical documentation in period defined by the Directive. Therefore, it is the responsibility of the manufacturer to plan and request extension of period of deposition of technical documentation in due time.

Fiditas confirms receipt of documentation, stores it in the archive and issues a Confirmation of deposit to the Client with document marking "FIDI yy ATEX Dxxx". The above information will be placed on the Confirmation of deposit of documentation issued by Fiditas.

7. OBJECTIONS, COMPLAINTS, DISPUTES AND WITHDRAWAL OF CERTIFICATES

Any objections/complaints the Client may have concerning the certificate issued or any other unfavorable decision made by Fiditas throughout the certification process, shall be submitted to Fiditas in writing. If the complaint is not in writing, Fiditas will proceed in the manner it deems appropriate. Unfavorable decisions include:

- denial of applications,
- refusal to continue an assessment,
- requirements for corrective actions,
- changes to the scope of assessment
- denial, suspension or withdrawal of the certificate,
- any other activities that prevent the Client from acquiring and/or maintaining certificate.

Fiditas will process the objections/complaints according to its procedure, which can be obtained on request. The complainant will be notified of Fiditas position on the matter in writing. Fiditas will attempt to resolve the issue by agreement within a reasonable timeframe, but no longer than 30 days. If the appeal/complaint is rejected, the Applicant may appeal to the Croatian Notified authority, the Impartiality Committee of Fiditas or, in the case of IECEx CoC, to IECEx and IEC in accordance with IEC CA 01 and IECEx 01.

Before a decision is reached, the information in the complaint is reviewed and analyzed, and the Client is informed of the results in writing. Records are kept on all complaints and actions implemented.

Any person or organization is free to express dissatisfaction to Fiditas (where a response is expected) regarding its activities or the activities of the manufacturer whose product has been certified by Fiditas.

Fiditas will assess the significance of the complaint and, if the complaint is justified, undertake the appropriate actions needed. The procedure of handling complaints is considered to be strictly privileged information, for the protection of both the complainant and Fiditas Clients.

Before a decision is reached, the information in the complaint is reviewed and analyzed, and the Client is informed of the results in writing. Records are kept on all complaints and actions implemented. Fiditas will attempt to resolve the issue by agreement within a reasonable timeframe, but no longer than 30 days.

If the complaint is not in writing, or is received from an unidentified source, Fiditas will proceed in the manner it deems appropriate. If such need is indicated, Fiditas will (with the permission of the complainant and the Client) stipulate the conditions under which the content and resolution of the complaint may become public information.

8. OTHER

Fiditas certificates that bear the accreditation symbol of the Croatian Accreditation Agency (HAA) are issued in accordance with accreditation regulations of HAA. However, it should not be assumed that the certificate has been approved by HAA.

Fiditas acceptance of a drawing showing marking details which include the European Community CE Marking should not be construed as implying that Fiditas gave their permission for the CE Marking to be applied to any particular product. Applying the CE Marking remains the sole responsibility of the Applicant in accordance with appropriate EU legislation.

IECEX logo shall only be used in accordance with IECEx Guide 01B, available at www.iecex.com .

9. USEFUL INFORMATION

List of EU harmonized standards for Directive 2014/34/EU:

https://ec.europa.eu/growth/sectors/mechanical-engineering/atex_en

List of a Clarification Sheets of ExNBG for Directive 2014/34/EU

https://ec.europa.eu/growth/sectors/mechanical-engineering/atex_en

and

https://www.vdtuev.de/SozEinrEmob_2013_2016/vdtuev-en/topics/industry/fire-and-explosion-protection/clarification-sheets-of-exnb-1

List of ExTAG Decision Sheets

<https://www.iecex.com/publications/extag-decision-sheets/>

Information on the current edition of international Ex standards and any Corrigendums, Amendments

<https://webstore.iec.ch/>