KSC POLAND Sp. z o.o.
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Certification Body

PC-OZ
PRODUCT CONFORMITY ASSESSMENT SCHEME

1. Purpose and scope

The purpose of this document is to define the principles of conformity assessment carried out by KSC POLAND Sp. z o.o., hereinafter referred to as the Notified Body, for equipment and protective systems intended for use in potentially explosive atmospheres based on the requirements of applicable conformity assessment procedures.

Appropriate documents are issued for all products covered by this scheme, confirming compliance with the requirements of the associated conformity assessment modules.

2. Legal and normative acts in the conformity assessment area

The mode of conducting conformity assessment processes at the Notified Body is based on the principles of assessment carried out by a third party and meets the conditions contained in the following provisions and standards:

1) Act of Parliament of 13 April 2016 on conformity assessment systems and market surveillance,
2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93,
3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC,
4) Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres,
5) ISO/IEC 17065 - Conformity assessment – Requirements for bodies certifying products, processes and services,
6) ISO/IEC 17067 – Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes,
7) ISO/IEC 17021-1 - Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements.

3. Scheme characteristics

This scheme offers compliance assessment processes for equipment intended for use in potentially explosive atmospheres of the following groups based on the associated modules:

Directive	*Product groups*	*Conformity assessment procedures (module)*
2014/34/UE	equipment-groups I and II, equipment-categories M1 and 1.	Annex III – **Module B** Annex IV – **Module D** Annex V – **Module F** Annex IX – **Module G**
	Internal combustion engines and electrical equipment of equipment-groups I and II, equipment categories M2 and 2	Annex III – **Module B** Annex VI – **Module C1** Annex VII – **Module E** Annex IX – **Module G**
	Other equipment of groups I and II, equipment categories M2 and 2	Article 13.1(b) (ii) – **Module A** and communication of the technical documentation Annex IX – **Module G**

Legend:

Module B – EU-Type Examination
Module C1 - Conformity to type based on internal production control plus supervised product testing
Module D - Conformity to type based on quality assurance of the production process
Module E - Conformity to type based on product quality assurance
Module F - Conformity to type based on product verification
Module G - Conformity based on unit verification

The customer chooses the appropriate module.

The Notified Body conducts conformity assessment to confirm compliance with the essential requirements of Directive 2014/34/EU according to technical specifications (harmonized standards) included in Annex 1 to this scheme.

If there is a need to assess compliance with other technical specifications for the above product groups according to this scheme, the Notified Body analyzes its capabilities (having competent personnel to conduct assessments and having research capabilities in the requested scope - *if applicable*) and then decides to extend/inability to extend the scope of this scheme.

4. Impartiality, confidentiality, competence

The Notified Body declares full impartiality and credibility.

The Notified Body acts as a third party, independent of the organization or product it assesses. The Notified Body, its top management and staff responsible for carrying out conformity assessment tasks are not designers, manufacturers, suppliers, installers, buyers, owners, users or conservators of the products they evaluate, or authorized representatives of the parties listed.
They not directly engage in the design, production or construction, marketing, installation, use or maintenance of these products, nor may they represent parties involved in such activities. They do not engage in activities that may threaten the independence of their judgments and credibility. This applies in particular to consulting services.

The Notified Body ensures that the activities of its subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.

Qualified, competent, having appropriate technical qualifications in a given field and extensive experience in the conformity assessment process, the Notified Body's personnel ensure that tasks are carried out reliably and objectively. Personnel are not subjected to any pressure or motivation, especially financial, that could affect their opinion or conformity assessment results.

The Notified Body, its top management and the specialists guarantee impartiality.

The salary of both top management and specialists performing the assessments does not depend on the number of assessments made or the results of those assessments.

By clearly defining the scope of responsibility, the information obtained in the compliance assessment process regarding the ownership of product documentation is fully confidential.

In order to confirm the competences held, the Notified Body meets the accreditation requirements set out in relevant accreditation standards harmonized to Regulation (EC) 765/2008 supplemented with additional requirements appropriate for assessing the competences of bodies performing the relevant conformity assessment procedures, according to the assignment given in the table below:

Module	***Module name***	***Accreditation standards harmonized with Regulation (EC) 765/2008 (+ additional requirements)***
Article 13.1(b) (ii)	Internal production control and communication of the technical documentation	ISO/IEC 17065
B	EU-Type Examination	ISO/IEC 17065 (ISO/IEC 17025 when testing is required)
C1	Conformity to type based on internal production control plus supervised product testing	ISO/IEC 17065 (ISO/IEC 17025 when testing is required)
D	Conformity to type based on quality assurance of the production process	ISO/IEC 17065 (+the ability to assess and approve manufacturers' quality systems where required. ISO-IEC 17021-1, point 9)
E	Conformity to type based on product quality assurance	ISO/IEC 17065 (+the ability to assess and approve manufacturers' quality systems where required. ISO-IEC 17021-1, point 9)
F	Conformity to type based on product verification	ISO/IEC 17065 (ISO/IEC 17025 when testing is required)
G	Conformity based on unit verification	ISO/IEC 17065 (ISO/IEC 17025 when testing is required)

5. The course of the conformity assessment process

The Notified Body grants all information in order to efficiently carry out the conformity assessment process.

Provides information about:

- regulations on conformity assessment,
- type and scope of laboratory tests needed to perform,
- test laboratories cooperating with the Notified Body that meet the requirements for performing tests for specific product groups,
- documentation necessary to carry out the conformity assessment,
- conformity assessment procedures at the Notified Body,
- using certification,
- fees,
- rules for suspending and withdrawing issued certificates,
- the possibility of appealing against decisions taken by the Notified Body

To obtain an offer for conformity assessment, the customer should specify the following information:

- the product(s) to be certified,
- the standards and/or other normative documents for which the client is seeking certification,
- the general features of the client, including its name and the address(es) of its physical location(s), significant aspects of its process and operations

The information obtained is reviewed to confirm that:

- the information about the client and the product is sufficient for the conduct of the certification process,
- any known difference in understanding between the Notified Body and the client is resolved, including agreement regarding standards or other normative documents,
- the scope of certification sought is defined,
- the means are available to perform all evaluation activities,
- the Notified Body has the competence and capability to perform the certification activity.

Based on the analysis of the information provided (by phone, paper, electronic or fax), the Notified Body decides to undertake / refuse to undertake the certification process and provides the manufacturer with information on possible prices for the service.

If the offer submitted is accepted, the manufacturer submits an application for assessment according to a specified conformity assessment procedure.

By submitting an application for conformity assessment, the manufacturer declares that:

- makes all necessary arrangements for the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and subcontractors, investigation of complaints and the participation of observers (if applicable)
- meets all applicable requirements set out in this scheme,
- the same application has not been lodged with any other Notified Body.

Detailed description of the procedures for the products conformity assessment is regulated in procedure P-9.2.1 "Products conformity assessment" taking into account the requirements contained in point 5.1÷ 5.7.

5.1 Internal production control and communication of the technical documentation

(Article 13.1 (b) (ii), Annex VIII to Directive 2014/34/UE)

Internal production control is the conformity assessment procedure whereby the manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s) and then communicate the technical documentation to a Notified Body, which shall acknowledge receipt of it as soon as possible and shall retain it.

No.	***step***	***Description***
1.	Submission and review of the application	Upon acceptance of the financial conditions, the manufacturer / the authorized representative submits an application for the storage of technical documentation, which is formally reviewed (does it contain all the necessary information for the process).
2.	Provision of technical documentation	The technical documentation provided must be properly secured against unauthorized access by third parties (e.g. sealed). The Notified Body adopts technical documentation in paper or electronic form.
3.	Acknowledge receipt	The confirmation uniquely identifies the product it covers and specifies the period of validity (the confirmation remains valid for a period of 10 years from the date of production of the last copy of the product. The manufacturer / authorized representative is obliged to inform the Notified Body about discontinuation of production).
4.	Retain of technical documentation	Technical documentation, at the request, can be supplemented, but cannot be returned. The manufacturer / authorized representative is obliged to inform about the date of introduction of the changes and to provide amended documentation to supplement the one already stored in the Notified Body.

The technical documentation shall contain at least the following elements:

a) a general description of the product,

b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

e) results of design calculations made, examinations carried out, etc., and

f) test reports.

5.2 EU-Type Examination
(Annex III to Directive 2014/34/EU)

EU-type examination (according to Directive 2014/34/EU) is the part of a conformity assessment procedure in which a Notified Body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of Directive that apply to it.

No.	Step	Description
1.	Submission and review of the application	Upon acceptance of the financial conditions, the manufacturer / an authorized representative submits an application for the EU-Type Examination, which is formally reviewed (does it contain all necessary information for the process). The application shall include: – the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well, – a written declaration that the same application has not been lodged with any other Notified Body, – the technical documentation that allows the conformity of the product with the applicable requirements of the directive to be assessed and includes the appropriate risk analysis and assessment. The technical documentation specifies the applicable requirements and covers, as far as is relevant for such assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements: a) a general description of the product, b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, d) a list of the harmonized standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonized standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied, e) results of design calculations made, examinations carried out, etc., and f) test reports, – the specimens representative of the production envisaged. The Notified Body may request further specimens if needed for carrying out the test program. The Notified Body accepts the possibility of delivering the results of the assessment / tests performed prior to submitting the application only in the case of confirmation of the competence of the assessor according to the applicable requirements of the standard EN ISO/IEC 17065, and in the case of conducting tests according to the applicable requirements of EN ISO / IEC 17025. If the evaluation / test results provided with the application are recognized, the Notified Body takes full responsibility for the presented results.

2.	Evaluation (assessment of technical documentation and product testing)	The Notified Body examines the technical documentation, verifies, whether, the given sample (s) have been produced in accordance with the technical documentation, and identifies the parts designed in accordance with the relevant provision of the relevant harmonized standards, as well as the parts that have been designed in accordance with the other relevant technical specifications. The Notified Body draws up a test program and has them performed to check if the manufacturer has chosen to apply the solutions set out in the relevant harmonized standards, whether these have been correctly applied or if the solutions aet out in relevant harmonized standards have not been applied, the solutions adopted by the manufacturer applying the other relevant technical specifications, meet the relevant essential health and safety requirements of the directive. Product tests are carried out by independent research laboratories accredited to the relevant extent. In the absence of relevant accredited laboratories, the Notified Body allows the possibility of conducting in other laboratories (including the manufacturer's laboratory) provided that the applicable technical requirements of ISO / IEC 17025 have been confirmed.
3.	Review of evaluation results and decision	A report is prepared from the analysis of all collected documents and an application for the issue / refusal to issue a certificate is prepared. Based on the review of all information provided and assessment results, a decision is made to issue or refuse to issue a certificate. The producer is informed about the decision taken (in the case of a positive decision, the decision is forwarded in the form of a certificate issued. In the event of a refusal, the producer will receive a written decision with detailed reasons.)
4.	Certificate	Where the type meets the requirements of Directive that apply to the product concerned, the Notified Body issue an EU-type examination certificate to the manufacturer
5.	Monitoring compliance and changes in the state of technical knowledge	The Notified Body informs the manufacturer about changes in certification requirements affecting the product that was subject to conformity assessment. If, during monitoring of compliance after issuing the certificate, the Notified Body finds that the product has ceased to meet the requirements, it calls on the Manufacturer to take appropriate corrective measures and, if necessary, suspends or withdraws the issued certificate.

The manufacturer is obliged to inform the Notified Body about all modifications of the approved type that may affect the compliance of the product with the essential health and safety requirements contained in the relevant directive or the conditions of its validity. Such modifications require additional approval in the form of an annex to the original EU type-examination certificate. The manufacturer shall keep a copy of the EU type-examination certificate and annexes with it along with technical documentation at the disposal of the national authorities for a period of 10 years after the product has been placed on the market.

5.3 Conformity to type based on quality assurance of the production process

(Annex IV to Directive 2014/34/EU)

Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the Notified Body assess the quality system to determine whether it satisfies the requirements referred to harmonized standard i.e. ISO/IEC 80079-34.

No.	*Step*	*Description*
1.	Submission and review of the application	Upon acceptance of the financial conditions, the manufacturer / authorized representative submits an application for assessment of his quality system with the Notified Body of his choice, for the products concerned, which is formally reviewed (does it contain all the necessary information for the process). The application shall include: a) the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well, b) a written declaration that the same application has not been lodged with any other Notified Body, c) all relevant information for the product category envisaged, d) the documentation concerning the quality system, e) the technical documentation of the approved type and a copy of the EU-type examination certificate.
2.	Quality system documentation	The quality system documentation shall permit a consistent interpretation of the quality programs, plans, manuals and records. It shall, in particular, contain an adequate description of: a) the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality, b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
3.	The auditing team	In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of Directive 2014/34/UE.

4.	Evaluation	The Notified Body assess the quality system to determine whether it ensures compliance of products with the type described in the EU-type examination certificate and with the requirements of Directive 2014/34/EU that apply to them. The audit include an assessment visit to the manufacturer's premises. The audit team reviews the technical documentation of product (s) in order to verify the manufacturer's ability to identify the relevant requirements of the directive and to carry out the necessary tests to ensure the conformity of the product (s) with these requirements.
5.	Decision	The Notified Body notifies the manufacturer of the assessment results. It provides him with an assessment report which includes the conclusions of the audit and the reasoned assessment decision.
6.	Quality Assurance Notification	In case of a positive decision, a Quality Assurance Notification is made covering the products certification by the manufacturer. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient. The manufacturer shall keep the Notified Body that has approved the quality system informed of any intended change to the quality system. The Notified Body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements or whether a reassessment is necessary.
7.	Surveillance	In accordance with the signed contract, the Notified Body carries out periodic surveillance audits. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. The manufacturer shall, for assessment purposes, allow the Notified Body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular: a) the quality system documentation, b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. From the carried out surveillance the Notified Body draws up and provides the manufacturer with an assessment report containing the conclusions from the audit. In addition, the Notified body may pay unexpected visits to the manufacturer. During such visits the Notified Body may, if necessary, outsource carrying out product testing, in order to verify that the quality system is functioning correctly. The Notified Body shall provide the manufacturer with an assessment report and, if tests have been carried out, with a test report.

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements that apply to them

The manufacturer shall affix the CE marking to each product, other than the component, which is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements.

The manufacturer takes all measures necessary for the production process and its monitoring.

Under the responsibility of the Notified Body and under its instructions, the manufacturer or his authorized representative shall affix its identification number to the CE marking during the production process.

5.4 Conformity to type based on product verification

(Annex V to Directive 2014/34/EU)

Conformity to type based on product verification is the part of a conformity assessment procedure whereby the Notified Body carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EU-type examination certificate and with the appropriate requirements.
The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out by examination and testing of every product.

No.	***Step***	***Description***
1.	Submission and review of the application	Upon acceptance of the financial conditions, the manufacturer / an authorized representative submits an application for product verification, which is formally reviewed (does it contain all the necessary information for the process). With the application the manufacturer provide to the Notified Body the EU type-examination certificate together with the approved technical documentation and the product (s) to verify compliance.
2.	Product tests	Based on the test program developed by the Notified body, all products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive 2014/34/UE. Product tests are carried out by independent research laboratories accredited to the relevant extent. In the absence of relevant accredited laboratories, the Notified Body allows the possibility of conducting tests in other laboratories (including the manufacturer's laboratory) provided that the applicable technical requirements of ISO / IEC 17025 have been confirmed.

3.	Review of test results and decision	Based on the review of all information provided and tests results, a decision is made to issue or refuse to issue a Certificate of conformity. The producer is informed about the decision taken (in the case of a positive decision, the decision is forwarded in the form of a certificate issued. In the event of a refusal, the producer will receive a written decision with detailed reasons).
4.	Certificate	If the products produced comply with the type described in the EU type-examination certificate and meet the applicable requirements for a given product, the Notified Body issues a Certificate of conformity to the manufacturer identifying approved products covered by it.

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements that apply to them

The manufacturer shall affix the CE marking on each item of product, other than a component, which conforms to the type described in the EU-type examination certificate and satisfies the applicable requirements. With the consent and responsibility of the Notified Body, the manufacturer may affix its identification number to products other than components.

5.5 Conformity to type based on internal production control plus supervised product testing

(Annex VI to Directive 2014/34/EU)

Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer or on his behalf, for each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out in order to verify conformity with the type described in the EU-type examination certificate and with the corresponding requirements. The tests shall be carried out under the responsibility of a Notified Body, chosen by the manufacturer.

No.	***Step***	***Description***
1.	Submission and review of the application	Upon acceptance of the financial terms, the manufacturer / authorized representative submits an application for the supervised product testing procedure which shall be reviewed. formally (does it contain all the necessary information for the process). With the application the manufacturer provide to the Notified Body the EU type-examination certificate together with the approved technical documentation.
2.	Product tests	For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the type described in the EU-type examination certificate and with the corresponding requirements of this Directive. The tests shall be carried out under the responsibility to the extent approved by the Notified Body.

		The customer can choose the following product test options: a) on-site assessment and testing to the extent approved by the Notified Body. The Notified Body agrees with the customer to evaluate an assessment and performs an on-site assessment to provide evidence that the manufacturer's testing process ensures the each unit produced will conform to the type described in the EU-type examination certificate. b) performance of tests by independent from the client, and appropriately accredited testing laboratories in the scope approved by the Notified Body. On the basis of the testing program approved by the Notified Body, the manufacturer orders the tests to be performed in a properly accredited testing laboratory.
3.	Review of test results and decision	Based on the review of all information provided and tests results, a decision is made on the compliance of manufactured products with the type described in the EU-type examination certificate. The producer is informed about the decision taken.
4.	Decision register	If the manufactured products comply with the type described in the EU type-examination certificate and meet the requirements applicable to a given product, the Notified Body registers the product serial numbers reported in the decision register and sends a written confirmation. In the event of a refusal, the producer will receive a written notification of detailed reasons.

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EU-type examination certificate and with the requirements that apply to them.

The manufacturer shall affix the CE marking to each product, other than the component, which is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements.

On the responsibility of the Notified Body manufacturer inserts its identification number during the production process.

5.6 Conformity to type based on product quality assurance

(Annex VII to Directive 2014/34/EU)

Conformity to type based on product quality assurance process is the part of a conformity assessment procedure whereby the Notified Body assess the quality system to determine whether it satisfies the requirements referred to harmonised standard i.e. EN ISO/IEC 80079-34.

No.	Step	Description
1.	Submission and review of the application	Upon acceptance of the financial conditions, the manufacturer submits an application for assessment of his quality system with the Notified Body of his choice, for the products concerned, which is formally reviewed (does it contain all necessary information for the process). The application shall include: a) the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well, b) a written declaration that the same application has not been lodged with any other Notified Body, c) all relevant information for the product category envisaged, d) the documentation concerning the quality system, e) the technical documentation of the approved type and a copy of the EU-type examination certificate.
2.	Quality system documentation	The quality system documentation shall permit a consistent interpretation of the quality programs, plans, manuals and records. It shall, in particular, contain an adequate description of: a) the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality, b) the examinations and tests that will be carried out before, during and after manufacture, c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and d) the means of monitoring the effective operation of the system.
3.	The auditing team	In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product (s) technology concerned, and knowledge of the applicable requirements of Directive 2014/34/UE.
4.	Evaluation	The Notified Body assess the quality system to determine whether it ensures compliance of products with the type described in the EU-type examination certificate and with the requirements of Directive 2014/34 / EU that apply to them. The audit include an assessment visit to the manufacturer's premises. The audit team reviews the technical documentation of the product (s) in order to verify the manufacturer's ability to identify the relevant requirements of the directive and to carry

		out the necessary tests to ensure the compliance of the product(s) with these requirements.
5.	Decision	The Notified Body notifies the manufacturer of the assessment results. It provides him with an assessment report which includes the conclusions of the audit and the reasoned assessment decision.
6.	Quality Assurance Notification	In case of a positive decision, a Quality Assurance Notification is made covering the products certification by the manufacturer. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient. The manufacturer shall keep the Notified Body that has approved the quality system informed of any intended change to the quality system. The Notified Body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements or whether a reassessment is necessary.
7.	Surveillance	In accordance with the signed contract, the Notified Body carries out periodic surveillance audits. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. The manufacturer shall, for assessment purposes, allow the Notified Body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular: a) the quality system documentation, b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. From the surveillance carried out by the Notified Body draws up and provides the manufacturer with an assessment report containing the conclusions from the audit. In addition, the Notified Body may pay unexpected visits to the manufacturer. During such visits, it may if necessary, have the product tested to verify that the quality system is functioning properly. The Notified Body shall provide the manufacturer with a assessment report and, if tests have been carried out, with a test report.

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EU-type examination certificate and with the requirements that apply to them.

The manufacturer affixes the CE marking to each product, other than the component, which is in conformity with the type described in the EU-type examination certificate and which satisfies the relevant requirements.

Under the responsibility of the Notified Body and under its instructions, the manufacturer affixes its identification number during the production process.

5.7 Conformity based on unit verification

(Annex IX to Directive 2014/34/EU)

Conformity based on unit verification is a conformity assessment procedure in which the manufacturer, under his sole responsibility, ensures and declares that the product that has been verified complies with the requirements of the directive that apply to it.

No.	Step	Description
1.	Submission and review of the application	Upon acceptance of the financial conditions, the manufacturer submits an application for unit verification, which is formally reviewed (does it contain all necessary information for the process). With the application the manufacturer provide to the Notified Body the technical documentation and the product (s) to verify compliance. The technical documentation shall contain at least the following elements: a) a general description of the product; b) conceptual design and engineering drawings and diagrams of components, sub-assemblies, circuits, etc.; c) descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the product; d) a list of the harmonized standards, applied in full or partially referenced in the Official Journal of the European Union, and, where these harmonized standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of the other relevant technical specifications used; in case of partial application of harmonized standards the technical documentation shall state which parts have been used; e) results of design calculations made, examinations carried out, etc.; f) test reports.
2.	Product tests	On the basis of the test plan developed by the Notified Body, the product specimen is subjected to the examination and appropriate tests specified in the relevant harmonized standards or equivalent tests specified in other relevant technical specifications. In the absence of such a harmonized standard, the body determines the tests to be performed. Product tests are performed by independent, accredited research laboratories. In the absence of accredited laboratories in the appropriate scope, the Notified Body allows for the possibility of testing in other laboratories (including the manufacturer's laboratory), provided that the applicable technical requirements of ISO / IEC 17025 have been confirmed.

3.	Review of test results and decision	Based on review of the information provided release decisions are made or refusal to issue a certificate of conformity for a given product. The producer is informed about the decision taken (in the case of a positive decision, the decision is forwarded in the form of a certificate issued. In the event of a refusal, the producer will receive a written decision with detailed reasons).
4.	Certificate	If the manufactured items meet the applicable requirements for a given product, the Notified Body issues a certificate of conformity to the manufacturer, identifying the item (s) of products covered by it.

The manufacturer affixes the CE marking to each item of product other than the component that complies with the applicable requirements.

Under the responsibility of the Notified Body and under its instructions, the manufacturer shall affix the Notified Body's identification number to each approved product.

6. Rights and obligations

6.1 Rights and obligations of the manufacturer

6.1.1 The manufacturer undertakes to:

a) always fulfils the certification requirements, including implementing appropriate changes when they are communicated by the Notified Body,
b) manufacturing the product in accordance with the technical documentation on the basis of which the Notified Body issued the certificate,
c) ensuring that the product meets the requirements underlying the certificate,
d) keep a copy of the certificate, technical documentation and all relevant documents for the period specified in the associated directive,
e) ensuring that the product covered by the certificate corresponds to the current state of technical knowledge,
f) maintaining records of all complaints that are known to him which relate to compliance with the requirements and will make them available to the Notified Body on request,
g) informs the Notified Body, without delay, of changes that may affect its ability to conform with the certification requirements (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),
h) suspension of placing on the market of certified products in which changes have been made until the approval of these changes in writing by the Notified Body,
i) discontinue any advertising activities that contain any reference to certification and take any other steps that are required after suspension, withdrawal or termination of certification,
j) when providing copies of certificates to others, copy them in full,
k) meet the requirements of the Notified Body and this scheme, citing product certification in the media, such as documents, brochures or advertising,
l) not using the certification of its products in a way that may discredit the Notified Body and not issuing statements related to the certification of its products in a way that the Notified Body would consider misleading or unauthorized

6.1.2 The manufacturer has right to:

a) referring to the certification granted in accordance with the scope of certification,
b) where applicable, placing on the marketed product (positive result of conformity assessment) the identification number of the Notified Body in accordance with the above modules / conformity assessment procedures.

6.2 Rights and obligations of the Notified Body

6.2.1 The Notified Body undertakes to:

a) keep confidential all information provided by the manufacturer during the conformity assessment process (excluding the information he is required to provide).
b) informing the Manufacturer about significant changes in legal requirements or changes in the state of technical knowledge that may affect the validity of the certificate,
c) confirming the validity of an existing certificate or issuing a new one if the Manufacturer reports changes to the approved type.
d) monitoring:
   - product compliance by verifying certification requirements,
   - the manufacturer's reference to the issued certificate in advertising materials, catalogs, website, declarations of conformity, etc.
   - changes in the client's ownership status,

- analyzes received by the Notified Body complaints,
- actions taken by the manufacturer as a result of complaints and other notifications

e) inform the notifying authority of the following:
- any refusal, restriction, suspension or withdrawal of a certificate,
- the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted,
- any circumstances affecting the scope of or conditions for notification,
- any request for information which they have received from market surveillance authorities regarding conformity assessment activities,
- on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

f) inform the other certification bodies of the following:
- concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued,

g) On request of the Commission and the Member States obtain a:
- copy of the EU-type examination certificates and/or additions thereto,
- copy of the technical documentation and the results of the examinations carried out.

***7.* Changes affecting certification**

In the case of changes affecting certification, the Notified Body informs the Customer about these changes, specifies the deadline for the changes and the conditions for checking the changes.
The actions to implement changes affecting certification include, if required, the following:

- tests,
- evaluation,
- review,
- decision,
- issuance of revised formal certification documentation to extend or reduce the scope of certification.

Within 20 days from the date of receipt of the above notifications, the Manufacturer will inform the Notified Body about his readiness to introduce changes and if all additional requirements are met by him within a specified period, a supplement to the certificate will be issued or annotations will be introduced to the product documentation archived in the Notified Body.
If the result of additional product checks proves to be unsatisfactory, the certificate will be restricted or suspended after the product has been assessed according to the changed requirements. If the Manufacturer notifies the Notified Body that he is not ready to make changes within a specified period, the certificate will be restricted or suspended immediately after obtaining this information.
The Notified Body stores all records related to activities undertaken in the above scope (including reasons for excluding any of the above-mentioned activities.

8. Extension, reduction, suspension or withdrawal of certification

Extension of the certification scope for products that meet the requirements of the same standards or other normative documents for varieties or versions of the same product that is certified, it is possible if these varieties do not differ significantly and meet all the requirements assigned to the basic product. The decision on the extension can be made by the CB Manager by establishing the scope of the simplified certification process, the content of the product documentation, tests to carried out.
The extension of the scope of the certificate has the form of a supplement to the certificate.

Reduction of the certification scope shall be used at the Manufacturer's request or when information appears that the conditions for holding the certificate have not been met.
Notified Body consider and decide upon the appropriate action include, if required, the following:

- tests,
- evaluation,
- review,
- decision,

issuance of revised formal certification documentation to extend or reduce the scope of certification.

Suspension of certification may take place in the event of temporary failure to meet the certification conditions. The decision to suspend the certificate is made by the CB Manager, providing the date of entry into force of this decision. In addition, its duration and conditions for restoring the certificate's validity are given. Conditions to restore validity may include (if required):

- tests,
- evaluation,
- review,
- decision.

If it is determined that the product may cause a threat to life or health, the CB Manager suspends the certificate immediately.
During the suspension period, the producer is obliged to suspend the marketing of the products to which the suspension applies and to use all advertising materials containing any reference to this certification.
Decisions and documents related to the procedure regarding suspension of certification are provided to the manufacturer in a documented manner and are attached to the documentation of the relevant certificate.
At the end of the certificate suspension period, the Notified Body checks whether the pre-specified conditions necessary to restore the validity of the certificate are met.
If these conditions are met, the validity of the certificate is restored, about what CB Manager notify the manufacturer in a documented manner.
The period of certificate suspension is included in its validity period.

Certification may be withdrawn:

- if the client did not take sufficient action in the event of suspension,
- if the standards or rules are changed and the manufacturer fails to ensure compliance with the new requirements,
- if the product is no longer manufactured or if the customer stops operating and reports the resignation from the certificate,
- if there is violation of the terms of the contract on how to use the certificate.

The decision about withdrawn of certification is provided to the manufacturer in a documented manner by CB Manager.

In the event of withdrawal of certification, the Customer is obliged to cease using all advertising materials containing any reference to this certification.

Reduction, suspension, withdrawal of certification is entered in the list of issued certificates.

9. Legal liability

The certificate obtained does not release the manufacturer from the product liability and the consequences of using the product of inadequate quality.

The certification process does not include the analysis of documentation of the subject of assessment in the light of applicable acts on copyright and related rights as well as on industrial property law.

10. Complains and appeals

The applicant, the certificate holder or other parties have the right to appeal in writing from the decision made by the Notified Body at each stage of the certification procedure or within the certificate validity period. All appeals and complaints of suppliers, organizations/clients, certificate holders are considered in the Notified Body in accordance with the principle of protection of interests of the supplier, organization/client.
The appeal should be filed with the CEO within 14 days from the date of receiving the decision.
The client will be informed about the result of the appeal proceedings within 30 days.
In the case of any disputes, the final decision is made by the Common Court with territorial jurisdiction over the registered office of Notified Body.

11. Public information.

The Notified Body keeps and publishes:

- information about certification activities,
- information about suspension or withdrawal of certification.

The Notified Body maintain information on certified products which contains at least the following:

- identification of the product;
- the standard(s) and other normative document(s) to which conformity has been certified;
- identification of the client

CB Manager provide information about the validity of a given certification.

Annex No 1

List of accredited activities conducted under flexible scope
according to which the Notified Body conducts conformity assessments to confirm compliance
with the essential requirements of the Directives

Legislation:
Directive 2014/34/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 equipment and protective systems intended for use in potentially explosive atmospheres

Product(s)	**module**	**Essential requirements or harmonized technical specification*):** **Product specification / Properties / Standards**
Group I – Electrical: - equipment-categories M1 - equipment-categories M2 - Safety devices, controlling devices and regulating devices - Components Group I – Non-electrical: - equipment-categories M1 - equipment-categories M2 - Safety devices, controlling devices and regulating devices - Components Group II gas - Electrical: - equipment-categories 1 - equipment-categories 2 - equipment-categories 3 - Safety devices, controlling devices and regulating devices - Components Group II gas – Non-electrical: - equipment-categories 1 - equipment-categories 2 - equipment-categories 3 - Safety devices, controlling devices and regulating devices - Components Group II dust – Electrical: - equipment-categories 1 - equipment-categories 2 - equipment-categories 3 - Safety devices, controlling devices and regulating devices - Components Group II dust – Non-electrical: - equipment-categories 1 - equipment-categories 2 - equipment-categories 3 - Safety devices, controlling devices and regulating devices - Components	EU-Type Examination *(Annex III – Module B)* Conformity to type based on quality assurance of the production process *(Annex IV – Module D)* Conformity to type based on product verification *(Annex V – Module F)* Conformity to type based on internal production control plus supervised product testing *(Annex VI – Module C1)* Conformity to type based on product quality assurance *(Annex VII – Module E)* Conformity based on unit verification *(Annex IX – Module G)* Internal production control and communication of the technical documentation *(Article 13.1(b) (ii))*	EN 1127-1:2019 EN 1127-2:2014 EN 1755:2015 EN 1834-1:2000 EN 1834-2:2000 EN 1834-3:2000 EN 14986:2017 EN 50303:2000 EN IEC 60079-0:2018 EN 60079-1:2014 EN 60079-2:2014 EN 60079-2:2014/AC:2015 EN 60079-5:2015 EN 60079-6:2015 EN 60079-7:2015 EN IEC 60079-7:2015/A1:2018 EN 60079-11:2012 EN 60079-15:2010 EN 60079-18:2015/A1:2017 EN 60079-25:2010 EN 60079-25:2010/AC:2013 EN 60079-26:2015 EN 60079-28:2015 EN 60079-30-1:2017 EN 60079-31:2014 EN 60079-35-1:2011/AC:2011 EN ISO/IEC 80079-34:2011 EN ISO/IEC 80079-34:2020 EN ISO 80079-36:2016 EN ISO 80079-37:2016 EN ISO/IEC 80079-38:2016/A1:2018

Limits of flexibility:

*) Use of appropriate normative documents appropriate to demonstrate compliance with the requirements applicable law.