



IECEX OPERATIONAL DOCUMENT

IEC System for Certification to Standards relating to Equipment for use
in Explosive Atmospheres (IECEX System)

IECEX Certified Equipment Scheme

**Guidance on the definition of 'manufacturer' in
relation to trade agents' and 'local assemblers'**



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX Operational Document 203

IECEX Certified Equipment Scheme

Guidance on the definition of ‘manufacturer’ in relation to ‘trade agents’ and ‘local assemblers’

Introduction

This document is supplementary to the IECEx rules, other IECEx operational documents and procedures operated by IECEx Certification Bodies (ExCBs), approved by the IECEx Management Committee to issue IECEx Certificates of Conformity (CoCs) for Equipment.

The purpose of this Operational Document is to ensure that each ExCB, accepted by the ExMC for the purposes of issuing IECEx CoCs, does so in a consistent manner.

This Operational Document, OD 203 provides guidance on the accepted definitions of the term ‘manufacturer’ in relation to ‘trade agents’ and ‘local assemblers’.

This Operational Document is intended to support the implementation of IECEx OD 009 and should be read in conjunction with the requirements defined in this document.

This document, prepared by ExMC Working Group 11 served as a report on the progress with Action Items 38 and 39 from the ExMC 2012 Calgary meeting and as further work on document ExMC/762/CD discussed in Calgary (refer Confirmed Formal Minutes as ExMC/819A/RM, Item 13.5). The document ExMC/891A/CD was submitted for consideration at the 2013 Fortaleza meeting of ExMC and endorsed for publication via Decision 2013/36.

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Guidance on the definition of ‘manufacturer’ in relation to ‘trade agents’ and ‘local assemblers’.

Scope

This operational document provides guidance on the ExMC accepted definitions of the terms ‘manufacturer’ used in the context the IECEx System in relation to ‘trade agents’ and ‘local assemblers’ and is published in two sections:

- SECTION 1 - Issue of IECEx Certificates of Conformity covering a distributor or agent who does not actually manufacture the equipment
- SECTION 2 - Use of a Local Assembler for final assembly and despatch of a product made from fully defined parts supplied by the manufacturer

This Operational Document is intended to support the implementation of IECEx OD 009 and should be read in conjunction with the requirements defined in this document.

This Operational Document should also be read in conjunction with the Basic Rules of the IECEx System, as detailed in Publication IECEx 01 and the Rules of Procedure of the IECEx Certified Equipment Scheme as detailed in Publication IECEx 02.

SECTION 1

Issue of IECEx Certificates of Conformity covering a distributor or agent who does not actually manufacture the equipment

1.1. Purpose

The purpose of this Section is twofold:

- To provide the Trade Agent with appropriate certification documentation, and a listing on the IECEx certificate database to allow the Trade Agent to present themselves to the market place as the de facto manufacturer.
- To enable the IECEx Scheme to have equal confidence in the conformity of products being placed on the market in the name of the Trade Agent as in products being placed on the market in the name of the original equipment manufacturer (OEM).

For the purpose of this document, the two companies involved are referenced as “Trade” and “OEM” respectively.

1.2. Background Information

Three circumstances or “Cases” exist in order to satisfy commercial needs in the market place:

Case 1

Where the name of the actual manufacturer (OEM) appears on the product and on the accompanying instructions, etc., in addition to the name of the distributor or agent.

Case 2

Where the name of the OEM does not appear on the product or on the accompanying instructions, etc., and the distributor or agent presents themselves to the market place as being the de facto manufacturer of the product. (Normally both the OEM and the distributor/agent would place equipment on the market under their respective names.)

Case 3

Where an OEM is manufacturing and certifying a product for another company as a subcontractor. (Only the distributor/agent places the product on the market).

For Case 1, the distributor or agent would normally rely entirely on the certificate which has been issued in the name of the manufacturer. If this is the case, no further action is required as it is entirely within the responsibility of the manufacturer to ensure that the distributor or agent assists the manufacturer in those duties related to the distribution and, potentially, recall of product.

For Case 2, the distributor or agent, in presenting themselves to the market as the de facto manufacturer, has to assume full responsibility for each product that is sold under their name. The OEM retains full responsibility for product sold under their name. Two separate certificates are issued for the same product, one in the name of the OEM and one in the name of the distributor/agent.

Case 3 is effectively a subset of Case 2, with only the distributor/agent presenting themselves to the market as the de facto manufacturer. The OEM does not place the

product on the market and does not have a certificate issued in their name. They do, however, have all other relevant documents (ExTRs and QARs) issued in their name.

This Operational Document is concerned only with Case 2 and, by extension, Case 3.

A number of IECEx Certification Bodies operate a procedure under local or regional certification. Terminology varies but includes terms such as “Certificate Transfer Procedure” and “Trade Agent Certification”.

For the purpose of this Operational Document, the company that finally places the product onto the market is considered to be a “Trade Agent” irrespective of the specific contractual arrangement with the actual manufacturer.

1.3. Procedure

1.3.1. The ExCB shall receive an application from Trade to issue a replica certificate showing the name of Trade as both applicant and manufacturer.

The application shall be accompanied by:

- The number of the IECEx Certificate issued to OEM (or the reference to the ExTR and QAR if a certificate has not been issued – Case 3)
- An alternative Type Designation, if required
- A declaration by OEM that the product to be placed on the market in the name of Trade will be identical to that described in the original IECEx Certificate (or ExTR – Case 3)
- A declaration by Trade that the product to be placed on the market in the name of Trade will be identical to that described in the original certificate (or ExTR – Case 3)
- A copy of the marking to be applied by OEM but showing Trade as the de facto manufacturer
- A copy of the contractual agreement between OEM and Trade

1.3.2. The ExCB shall record in the form of an ExTR that the items in 1.3.1 have been checked. The marking shall be recorded in the report, along with reference to checking the contents of the instruction document to be supplied by Trade. The report need not contain any technical information beyond referring directly to the original report and certificate (Case 2) prepared for OEM. Only “Trade” will be shown on the summary sheet of the EXTR which will be published on the IECEx web site.

1.3.3. The ExCB shall conduct an assessment of Trade in accordance with the relevant requirements of ISO/IEC 80079-34 (See Annex A) and shall issue a QAR. The QAR document shall fully document the proof of Trade to comply with the information at 1.3.1, and provide confirmation that a QAR is in place for OEM to make the product. Only Trade will be shown on the QAR summary which will be published on the IECEx web site.

The QAR Summary on the IECEx web site shall not note the restricted nature of the report and the cross reference to the QAR issued to OEM will be given in the complete document which will be available for other CBs but not to the public so that the currency of the relevant QAR can be checked.

1.3.4. The ExCB shall prepare a new IECEx Certificate which is identical to the certificate issued to OEM (Case 2) except that the name and address of Trade is substituted, the revised Type Designation is given, if relevant, and the ExTR and QAR numbers are those created as a result of the activity at 1.3.2 and 1.3.3.

1.4. Involvement of more than one ExCB

The basic process outlined above is based on a single ExCB being responsible for all certificates, ExTRs and QARs.

In practice, up to three ExCBs may be involved, although roles may be combined.

For the purpose of explanation:

- ExCB1 is responsible for issuing all ExTRs and certificates.
(Note: It is not envisaged that the certificates issued to OEM and Trade will be issued by different ExCBs.)
- ExCB2 is responsible for all QAR activity at OEM.
- ExCB3 is responsible for all QAR activity at Trade.

As the certificate issuing body, ExCB1 has overall responsibility to ensure that ExCB2 and ExCB3 have covered all relevant activities of OEM and Trade respectively, prior to issuing the certificates and on a continuing basis.

ExCB2 has the additional responsibility of ensuring that OEM's procedures include correct interfacing with Trade in respect of any "after-sales" issues, such as product recall.

ExCB3 has the responsibility to ensure that Trade has the capabilities to undertake the QA responsibilities outlined in **Annex A** as a subset of ISO/IEC 80079-34 and that the documentation outlined in 1.3.2 remains valid.

ExCB2 and ExCB3 cross refer to the corresponding QAR for Trade and OEM respectively when completing their QAR for OEM and Trade. This cross reference is not included in the QAR summary on the IECEx web site.

SECTION 2

Use of a Local Assembler for final assembly and despatch of a product made from fully defined parts supplied by the manufacturer

2.1. Purpose

The purpose of this Operational Document is to provide a coherent mechanism whereby such a normal industrial practice can be extended to the final assembly of some forms of Ex Equipment.

2.2. Background Information

For simple cases where a manufacturer is fully responsible for the design of various assemblies, using components or sub-assemblies which are entirely within its control, the physical final assembly of such items is often performed at a remote location of the manufacturer or by an agent of the manufacturer. Such an activity might comprise, for example, the fitting of the correct number of terminals to a junction box, in furtherance of a specific customer order.

2.3 Procedure

- 2.3.1. In all cases where the use of a Local Assembler (LA) is envisaged, the manufacturer shall make an application to the ExCB that is responsible for the issue and maintenance of the QAR. The application shall be accompanied by the written procedure that the manufacturer intends to use to ensure that the product despatched from the LA conforms to a design permitted by the certification documents and which describes the process to ensure that the requirements of this OD are complied with.
- 2.3.2. The ExCB shall process the application as an extension to scope of the QAR, seeking sufficient information that the proposed procedure can be correctly implemented. Whether this is done in association with a full QAR or as a desk exercise between full QARs, this extension to scope shall be added to the QAR summary on the IECEx web site, by inserting the relevant information for each Local Assembler (name, address, limitation of scope) in the Comment field of the web site summary.
- 2.3.3. Operation of the procedure shall be monitored along with all other relevant aspects as part of routine surveillance and assessment of the manufacturer, at which time evidence of correct operation of the agreed procedure shall be obtained. Where a manufacturer uses more than one Local Assembler, the ExCB assessment shall confirm that the internal audit process of the manufacturer audits the operation of procedures with every assembler.
- 2.3.4. The manufacturer's written procedure shall include at least the following:
 - A statement of how the contract is drawn up between the manufacturer and the assembler to ensure that the assembler accepts responsibility for its part in the process.
 - The process used to ensure that the assembler is issued with all appropriate assembly instructions.
 - The process used to transfer identified components of the permitted assemblies to the assembler, including evidence that the assembler has correctly received undamaged components and retains any necessary identification of the components prior to assembly.
 - The process used to ensure that the assembler applies correct final marking to the assembly and includes relevant documentation with each assembly delivered to a customer.

- The process of final inspection to be employed by the assembler and the transmission of appropriate records to the manufacturer. These records shall be sufficient for the manufacturer to operate an efficient product recall system and will transfer any information related to customer complaints. Records shall also be transmitted and retained of any faulty items received from the manufacturer.
- The process for subsequently identifying which assembler finally placed the product on the market under the authority of the manufacturer. Note: The method of identification is not prescribed by this OD but might include, for example, a code contained within the product serial number.

2.3.5. The following are noted as specific limitations in application of this Operational Document:

- 2.3.5.1. The Local Assembler shall have either an appropriate QAR issued by an ExCB or an ISO 9001 Quality Management System Certificate issued by a certification body that has been accredited for the purpose by a member body of the IAF and which specifically covers activities related to the particular assembly process.
- 2.3.5.2. The Local Assembler shall not machine Flameproof (Ex d) Enclosures, but may add holes (for example, for cable entry devices or for switch operators) to an Increased Safety (Ex e) Enclosure.
- 2.3.5.3. The Local Assembler shall use only parts supplied direct by the manufacturer unless, by prior agreement with the manufacturer, local sourcing of certain items is agreed. Such locally sourced items may include fully defined standard industrial items, such as screwed fasteners, or items clearly defined by reference to an IECEx Certificate, such as Component Certified terminals to be inserted in a junction box. Items which might directly affect the explosion protection (other than identified by an IECEx Certificate) shall not be locally sourced, for example gasket materials.
- 2.3.5.4. The manufacturer shall perform a physical inspection of a sample item produced by the assembler, prior to initiating production release of items of the same general type.
- 2.3.5.5. If internal wiring of equipment is included in the scope of the activity, routing and full definition of the wiring shall form part of the information provided by the manufacturer.
- 2.3.5.6. The manufacturer shall ensure, either directly or by a process agreed with the assembler, that all the assembler's personnel that will have an input potentially affecting conformity of the final product have adequate training in the relevant aspects of explosion protection, in interpreting the manufacturer's drawings and process instructions, and in the reasons why the documentation process is important. In particular, all personnel shall understand that failure to follow the manufacturer's detailed instructions, in any way, will result in the production of uncertified equipment.

ANNEX A

If Trade already has a full QAR covering the type of equipment for which they are acting as Trade Agent, this should cover all the technical aspects other than ensuring that the commercial contracts are appropriately referenced in the individual QA systems and that the two QARs cross refer to each other.

If Trade does not already have an appropriate QAR, a truncated evaluation needs to be performed, based on inclusion of the following aspects from ISO/IEC 80079-34:

Organisation and Quality System

- 1) Certain responsibilities should be defined. (See ISO/IEC 80079-34 5.5.1 a), b), c), and f)).
- 2) Compliance of equipment with the certified design should be a quality objective and a stated purpose of the Quality System. Also, complying with the requirements of ISO/IEC 80079-34 should be a stated intention.
- 3) Management Reviews should address certified products (see ISO/IEC 80079-34 5.6.1 and 5.6.2 for details).
- 4) Internal audits should address certified products (see ISO/IEC 80079-34 8.2.2 for details).

Control of documents

- 5) The procedures for document control should include a number of things relating to certified products. (See ISO/IEC 80079-34 4.2.3 a), c) and f) for details.)
Note: Sales Literature and User/Installation Instructions are examples of “Manufacturers Documents” likely to be included.

Control of records

- 6) The procedures for control of records should include a number of things relating to certified products. (See ISO/IEC 80079-34 4.2.4 for details.)

Product realisation

- 7) The following aspects are relevant
 - a) Identifying customer’s requirements for hazardous area products. (ISO/IEC 80079-34 7.2.1).
 - c) Reviews to ensure customer’s requirements are compatible with the Type Examination Certificate. (ISO/IEC 80079-34 7.2.3)
 - d) Agreed arrangements with the equipment manufacturer, to give evidence the product complies with his equivalent Certificate.
 - e) Product identification. (ISO/IEC 80079-34 7.5.3 a)).
 - f) Traceability. (ISO/IEC 80079-34 7.5.3 b)).
 - g) Provision of instructions to the customer. (ISO/IEC 80079-34, 7.5.5).

Control of nonconforming product

- 8) The procedures for control of nonconforming product should include product recall (ISO/IEC 80079-34 8.3 a) to e)).

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