



ExMC/1299/DV
October 2017

**INTERNATIONAL ELECTROTECHNICAL COMMISSION SYSTEM FOR
CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE
IN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

Title: Scope Extension Assessment Report for Eurofins Electrosuisse Product Testing AG, an Accepted ExCB and ExTL to include ISO 80079-36 and ISO 80079-37 within the IECEx System, Equipment Scheme 02

To: Members of the IECEx Management Committee, ExMC

Introduction

Following an application for a scope extension by Eurofins Electrosuisse Product Testing AG, to include ISO 80079-36 and ISO 80079-37 within their scope, a special site assessment visit was arranged and conducted.

At the time of the assessment the organisation was known as Electrosuisse but it has since been acquired by Eurofins and is now known as Eurofins Electrosuisse Product Testing AG. The Secretariat has confirmed that there have been no changes to the staff, location, facilities or processes as a result of this change.

This report details the assessment findings of this scope extension with the IECEx Assessment Team recommending the acceptance of the above scope extension.

It is now hereby submitted for voting by ExMC.

Please consider the report and return the completed voting form, separate Word Document, to the Secretariat **Chris Agius** by **2017 11 20**.

Your speedy response to the voting process will be very much appreciated.

Chris Agius

IECEx Secretary

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ExMC/1299/DV
October 2017

IEC System for certification to standards relating to equipment for use in Explosive Atmospheres (IECEX System)

IECEX Assessment Report Form

IECEX Assessment Report Form for use by IECEX Assessment Teams to report Assessments conducted according to the IECEX Assessment Procedures of

- a) Operational Document IECEX OD 003-2 for the Certified Equipment Scheme
 - b) Operational Document IECEX OD 016 for the Certified Service Facility Scheme
 - c) Operational Document IECEX OD 022 for the IECEX Conformity Mark Licensing System
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IECEX ExCB/ExTL assessment report for Eurofins Electrosuisse Product Testing AG

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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1 Assessment information

1.1 Type of Body covered by this assessment: <retain appropriate marks>

ExCB for IECEx Certified Equipment Scheme	✓
ExTL for IECEx Certified Equipment Scheme	✓
ExCB for IECEx Certified Service Facilities Scheme	
ExCB for IECEx Conformity Mark Licensing System	

NOTE 1 ExCB - IECEx Certification Body

NOTE 2 ExTL - IECEx Testing Laboratory

1.2 Type of assessment: <retain appropriate marks>

Pre-assessment for candidate body	
Initial assessment for candidate body	
Surveillance	
Re-assessment	
Scope extension	✓

This site assessment was conducted for the processing of a scope extension request from Eurofins Electrosuisse Product Testing AG for inclusion of the ISO 80079-36 and -37 non-electrical Standards.

1.3 Details of body

1.3.1 Country

Switzerland

1.3.2 Name of body

Eurofins Electrosuisse Product Testing AG

1.3.3 Name and title of nominated principal contact

Name	Title	E-mail address
Jürg Rellstab	Head of Product Certification	juergrellstab@eurofins.ch

1.4 Assessment information

1.4.1 Members of the assessment team

Name	Role (modify as necessary)
Ron Webb	Lead Assessor

1.4.2 Place(s) of assessment

Luppenstrasse 1, CH-8320 Fehraltorf, Switzerland

1.4.3 Assessment date

29-30 September 2016 and follow-up activities

1.5 Scopes

1.5.1 Additional Standards for ExCB scope for equipment certification scheme

Number	Title
ISO 80079-36 Edition 1 (2016)	Explosive atmospheres - Part 36: Non-electrical equipment for explosive atmospheres - Basic method and requirements
ISO 80079-37 Edition 1 (2016)	Explosive atmospheres - Part 37: Non-electrical equipment for explosive atmospheres - Non electrical type of protection constructional safety "c", control of ignition source "b", liquid immersion "k"

1.5.2 Additional Standards for ExTL scope for equipment certification scheme

Number	Title
ISO 80079-36 Edition 1 (2016)	Explosive atmospheres - Part 36: Non-electrical equipment for explosive atmospheres - Basic method and requirements
ISO 80079-37 Edition 1 (2016)	Explosive atmospheres - Part 37: Non-electrical equipment for explosive atmospheres - Non electrical type of protection constructional safety "c", control of ignition source "b", liquid immersion "k"



2 Common information

2.1 Legal entity of body

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.2 Financial support

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.3 History

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.4 Documentation

2.4.1 Quality manual

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.4.2 Procedures

While covered in the assessment reported in ExMC/983/DV, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

2.4.3 Work instructions

While covered in the assessment reported in ExMC/983/DV, it was confirmed that the procedures also cover the new Standards listed under the scope extension request. There are some new Work instructions covering the electrostatic tests

2.4.4 Records (including test records where relevant)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.4.5 Document change control

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.5 Confidentiality

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.6 Publications (Hard cover and Electronic)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.



2.7 Recognition and agreements

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.8 Internal audit and periodic management review

While covered in the assessment reported in ExMC/983/DV, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

2.9 Contracting, subcontracting, use of other labs and use of other locations

No subcontracting for the standards considered

2.10 Training and competence

There is a competency matrix for the IECEx Scheme. Interviews were undertaken with staff to ensure that they had the required level of understanding. These are included in a TCD document which is held by the Secretariat. Training records for each staff member are held on an Intranet system and are very comprehensive.

2.11 Complaints and appeals (including appeals to IECEx)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

2.12 Special facts to be noted

2.12.1 Supporting documentation

Copies of additional supporting information for this assessment have been provided to the applicant and the IECEx Secretariat. These are included in a site assessment report and include:

- Completed technical capability document (TCD)

2.13 Recommendations

Based on the assessment performed Eurofins Electrosuisse Product Testing AG is recommended for scope extension to include the Standards listed in 1.5 in the IECEx scheme as:

- An ExCB in the IECEx Certified Equipment Scheme
- An ExTL in the IECEx Certified Equipment Scheme

with the extension of scope as detailed in section 1.5.

Ron Webb

Lead Assessor



3 ExCB for IECEx Certified Equipment Scheme

3.1 Assessment references

- a) IECEx02 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
- b) OD003-2 Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
- c) OD005-2 IECEx Quality System Requirements for Manufacturers – Part 2: Audit Checklist. (This is available in a Word format for use by ExCBs)
- d) ISO/IEC 80079-34 Edition 1, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture
- e) OD009 Issuing of CoCs, ExTRs and QARs
- f) IECEx Document OD 025 Guidelines on the Management of Assessment and Surveillance programs for the assessment of Manufacturer's Quality Systems in accordance with the IECEx Scheme
- g) OD0026 IECEx Certified Equipment Scheme – Guidelines for the qualification of Lead Auditor and Auditors, in accordance with the IECEx System
- h) ISO/IEC 17065, General requirements for bodies operating product certification systems
- i) IECEx Document OD17 Drawing and documentation guidance
- j) IECEx OD 280 Ed.1 and ExMC/1031A/CD

NOTE The latest editions of the above documents were applied

3.2 Candidate ExCB persons interviewed

Name	Position
Jürg Rellstab	Head of Product Certification

3.3 Associated ExTL(s)

The ExCB is integral with the ExTL

3.4 Associated certification functions

While covered in the assessment reported in ExMC/983/DV, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

3.5 National marks and certificates

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

3.6 Standards accepted in scope extension

See clause 1.5 of this report

3.7 National differences to IEC standards

National differences to IEC standards are those for the European differences listed in the latest version of the IECEx Scheme Bulletin.

3.8 Organisation

3.8.1 Names, titles and experience of the senior executives

Name	Title	Experience
Jürg Rellstab	Head of Product Certification	12 years in Certification, 12 years at Eurofins Electrosuisse Product Testing AG

3.8.2 Name, title and experience of the quality management representative

Name	Title	Experience
Bernardo Rieder	Quality Manager	15 years at Eurofins Electrosuisse Product Testing AG, 13 years in the field of Quality Management

3.8.3 Name and title of signatories for certification

Name	Title
Jürg Rellstab	Head of Product Certification
Martin Pluess	Certification engineer

3.8.4 Other employees in ExCB activity

Name
Hans-Peter Leserf

3.9 Organizational structure

Included in the Site Assessment Report

3.10 Administration

3.10.1 Administrative structure

Included in the Site Assessment Report

3.10.2 Indemnity insurance

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

3.11 Resources

Adequate staffing resources were available

3.12 Committees (such as governing or advisory boards)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.



3.13 Certification operations

3.13.1 National approval/certification methods

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

3.13.2 Certification policy

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

3.13.3 Application for certification

While covered in the assessment reported in ExMC/983/DV, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

3.13.4 Certification decision

While covered in the assessment reported in ExMC/983/DV, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

3.13.5 Suspension and cancellation of certificates

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/983/DV.

3.14 Certificates issued

Eurofins Electrosuisse Product Testing AG are able to demonstrate experience with non-electrical standards, noting the number of certificates and reports issued under the ATEX Directive:

Standard numbers	Type of protection or other identifying information	Total
EN 13463-xx	Non-electrical equipment (ATEX Certificates)	21

3.15 National accreditation

Eurofins Electrosuisse Product Testing AG are a Notified body for the ATEX Directive Notified Body Number 1258. They have ISO/IEC 17065 accreditation from SAS valid from 24 09 2016 to 23 09 2021.

3.16 Assessment of manufacturers and issue of QARs

Eurofins Electrosuisse Product Testing AG already carry out QAN assessment to ATEX for non-electrical equipment. This will extend to cover QARs under the IECEx Scheme.

3.17 Comments (including issues found during assessment)

The staff interviewed had a good understanding of the non-electrical standards ISO 80079-36 and ISO 80079-37 due to their experience with the EN13463-xx series, which were used as a basis for development of ISO 80079-36 and ISO 80079-37.



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A review of previous files relating to the EN 13463 series revealed that Eurofins Electrosuisse Product Testing AG staff are well versed and have a full understanding of the assessment approaches for non-electrical equipment for Ignition Hazard Assessments.

4 ExTL for IECEx Certified Equipment Scheme

4.1 Assessment references

- a) IECEx02 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
- b) IECEx OD003-2 Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
- c) IECEx OD009 Issuing of CoCs, ExTRs and QARs
- d) ISO/IEC 17025:2005 Edition 2, General requirements for the competence of testing and calibration laboratories
- e) IECEx Document OD17 Drawing and documentation guidance
- f) IECEx Technical Capability Document (TCD)
- g) ExTAG decision sheets (DSs)
- h) IECEx OD 280 Ed.1 and ExMC/1031A/CD

NOTE The latest editions of the above documents were applied.

4.2 Candidate ExTL persons interviewed

Name	Position
Christian Ettlin	Test engineer
Thomas Koehntopp	Test engineer
Urban Strebel	Test engineer
Stefan Hartmann	Test engineer

4.3 Associated ExCB(s)

The ExCB is integral with the ExTL

4.4 Organisation

4.4.1 Names, titles and experience of the senior executives

Name	Title	Experience
Jürg Rellstab	Head of Product Certification	12 years in Certification, 12 years at Eurofins Electrosuisse Product Testing AG

4.4.2 Name, title and experience of the quality management representative

Name	Title	Experience
Bernardo Rieder	Quality Manager	15 years at Eurofins Electrosuisse Product Testing AG, 13 years in the field of Quality Management



4.4.3 Other employees in ExTL activity

Name
Ronny Hornbogen

4.5 Organizational structure

Included in the Site Assessment Report

4.6 Resources

Adequate staff resources are available

4.7 Test reports issued

Number of test reports (ExTRs) issued under for the preceding four years for each type of protection.

Eurofins Electrosuisse Product Testing AG are able to demonstrate experience with non-electrical standards, noting the number of certificates and reports issued under the ATEX Directive:

Standard numbers	Type of protection or other identifying information	Total
EN 13463-xx	Non-electrical equipment (ATEX)	21

4.8 National accreditation

Eurofins Electrosuisse Product Testing AG are a Notified body for the ATEX Directive Notified Body Number 1258. They have ISO/IEC 17025 accreditation from SAS valid from 24 09 2016 to 23 09 2021.

4.9 Calibration

While covered in the assessment reported in ExMC/983/DV, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

4.10 Comments (including issues found during assessment)

The staff interviewed had a good understanding of the non-electrical standards ISO 80079-36 and ISO 80079-37 due to their experience with the EN13463-xx series, which were used as a basis for development of ISO 80079-36 and ISO 80079-37.

It is further acknowledged that Eurofins Electrosuisse Product Testing AG are an active ExTL with an extensive scope of acceptance, refer to IECEx OD 001, therefore are in possession of the necessary test equipment and resources to undertake tests according to ISO 80079-36 and 80079-37.