**INTERNATIONAL ELECTROTECHNICAL COMMISSION IEC SYSTEM FOR**

**CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN**

**EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

**TITLE: IECEx Assessment Report for an extension of scope for Ex-Agencija- Agencija za prostore ugrožene eksplozivnom atmosferom, HR, an existing Accepted Ex Certification Body (ExCB) and an Accepted Ex Test Laboratory, ExTL, within the IECEx System, Equipment Scheme 02, to include IEC 60079-28, within their scope.**

**INTRODUCTION**

This document contains the IECEx Assessment Report for ExA, HR, an existing Accepted Ex Certification Body (ExCB) and an Accepted Ex Test Laboratory ExTL, within the IECEx System, Equipment Scheme 02, to include IEC 60079-28 within their scope.

The report is hereby submitted for voting by the ExMC by

**2018 09 10**

**Chris Agius**

**IECEx Secretariat**

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| --- | --- |
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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

1. Operational Document IECEx OD 003-2 for the Certified Equipment Scheme
2. Operational Document IECEx OD 016 for the Certified Service Facility Scheme
3. Operational Document IECEx OD 022 for the IECEx Conformity Mark Licensing System

IECEx ExCB/ExTL assessment report for

Ex-Agencija- Agencija za prostore ugrožene eksplozivnom atmosferom

Industrijska 25
HR-10431 Sveta Nedelja

Croatia

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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# Assessment information

## Type of Body covered by this assessment:

|  |  |
| --- | --- |
| 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

## Type of assessment: <retain appropriate marks>

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

## Details of body

### Country

Croatia

### Name of body

Ex-Agencija - Agencija za prostore ugrožene eksplozivnom atmosferom

### Name and title of nominated principal contact

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **E-mail address** |
| Stipo Đerek | Director of Sector for Certification and Testing | s.derek@ex-agencija.hr |

## Assessment information

### Members of the assessment team

|  |  |
| --- | --- |
| **Name**  | **Role (modify as necessary)** |
| Thierry Houeix (INERIS) | Lead assessor |

### Place(s) of assessment

Industrijska 25
HR-10431 Sveta Nedelja
Croatia

### Assessment date(s)

16 April 2018

## Scope

### ExCB scope for equipment certification scheme

| **Number**  | **Title**  | **Scope** |
| --- | --- | --- |
| IEC 60079-28 Ed. 2 | Explosive atmospheres - Part 28: Protection of equipment and transmission systems using optical radiation | Extension |

### ExTL scope

The ExTL scope is the same as for the ExCB.

# Common information

## Legal entity of body

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Financial support

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## History

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Documentation

### Quality manual

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

### Procedures

The new standard has been incorporated into the Ex-Agencija manual and use documented procedures. The documents were checked during the assessment and found to meet the requirements of the IECEx

### Work instructions

Work instructions are included in the documents mentioned above.

### Records (including test records where relevant)

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

### Document change control

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Confidentiality

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Publications (Hard cover and Electronic)

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Recognition and agreements

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Internal audit and periodic management review

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

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

Ex-Agencija has an agreement with FTZU for the tests required by IEC 60079-28 for the type of protection op sh and op pr. They can use this agreement if needed.

## 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. During the interviews the staff demonstrated their knowledge and competence in the application of IEC 60079-28.

## Complaints and appeals (including appeals to IECEx)

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Special facts to be noted

### 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:

* Details of issues raised and how these have been resolved
* Assessors’ notes
* TCD

## Recommendations

Based on the assessment performed on 16 April 2018, Ex-Agencija- Agencija za prostore ugrožene eksplozivnom atmosferom is recommended for continued acceptance in the IECEx scheme as ExCB and ExTL for:

* + Extension of IEC60079-28

This is according to the scope of the standards listed in OD 001 including the extension of scope.

|  |  |
| --- | --- |
| Thierry Houeix |  |
| Lead Assessor |  |

Date: 23 May 2018

# ExCB for IECEx Certified Equipment Scheme

## Assessment references

1. IECEx02IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
2. OD003-2Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
3. OD005-1IECEx Quality System Requirements for Manufacturers – Part 1: Guidance on the establishment and maintenance of a quality system
4. OD005-2IECEx Quality System Requirements for Manufacturers – Part 2: Audit Checklist.(This is available in a Word format for use by ExCBs)
5. ISO/IEC 80079-34 Edition 1, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture
6. OD009 Issuing of CoCs, ExTRs and QARs
7. IECEx Document OD 025Guidelines on the Management of Assessment and Surveillance programs for the assessment of Manufacturer’s Quality Systems in accordance with the IECEx Scheme
8. OD0026IECEx Certified Equipment Scheme – Guidelines for the qualification of Lead Auditor and Auditors, in accordance with the IECEx System
9. ISO/IEC 17065, General requirements for bodies operating product certification systems
10. IECEx Document OD17 Drawing and documentation guidance
11. IECEx Technical Capability Documents (TCD)
12. ExTAG decision sheets (DSs)

NOTE The latest editions of the above documents were applied

## ExCB persons interviewed

|  |  |
| --- | --- |
| Name | Position |
| Damir Korunić | Director General |
| Slobodon Sertić | Head of Laboratory |
| Stipo Đerek | Director of Sector for Certification and Testing |
| Marko Ružić | Quality Manager and Lead Auditor for IECEx |
| Ana Hađak | Certification engineer  |
| Ivan Stepanić | Certification engineer |
| Rikard Slunjski | Certification engineer |

## Associated ExTL(s)

The ExTL is integral with the ExCB.

## Associated certification functions

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## National marks and certificates

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Standards accepted

See clause 1.5.1 of this report and OD 001

## National differences to IEC standards

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Organisation

### Names, titles and experience of the senior executives

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Experience****Ex/Overall** |
| Damir Korunić | Director General  | 18 years in Ex |
| Stipo Đerek | Director of Sector for Certification and Testing | 24 years in Ex |
| Slobodon Sertić | Head of Laboratory | 34 years in Ex |

### Name, title and experience of the quality management representative

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Experience**  |
| Marko Ružić | Director Quality  | 14 years  |

### Name and title of signatories for certification

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Comments** |
| Damir Korunić | Director General  | 18 years in Ex |
| Stipo Đerek | Director of Sector for Certification and Testing | 24 years in Ex |

### Other employees in ExCB activity

|  |
| --- |
| **Name** |
| There are several employees with appropriately designated competencies in Ex who may be used in an ExCB role for a project provided, they have not been used in an ExTL role for that project |

## Organizational structure

See in Annex A

## Administration

### Administrative structure

Sufficient administrative assistance is provided

### Indemnity insurance

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Resources

Ex-Agencija - Agencija za prostore ugrožene eksplozivnom atmosferom have an adequate number of staff for the current level of business.

## Committees (such as governing or advisory boards)

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Certification operations

### National approval/certification methods

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

### Certification policy

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

### Application for certification

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

### Certification decision

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

### Suspension and cancellation of certificates

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Certificates issued

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## National accreditation

Application for National accreditation for standard involved in this scope extension has been made. The next surveillance will include IEC 60079-28. Due to the fact it is not today included annual IECEx surveillance is required,

## Assessment of manufacturers and issue of QARs

Ex-Agencija already carry out QAN assessment of electrical and non-electrical equipment. This will be extended to cover QARs of products in accordance with IEC 60079-28. A training session for QA auditors will be undertaken when a product requiring compliance to IEC 60079-28 will be assessed.

## Comments (including issues found during assessment)

Minor issues were found during the site assessment visit which were cleared to the satisfaction of the assessment team during the visit relating to QAR issue.

No issues requiring action remained after the site visit.

# ExTL for IECEx Certified Equipment Scheme

## Assessment references

1. IECEx02 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
2. IECEx OD003-2 Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
3. IECEx OD009 Issuing of CoCs, ExTRs and QARs
4. ISO/IEC 17025:2005 Edition 2,General requirements for the competence of testing and calibration laboratories
5. IECEx Document OD17 Drawing and documentation guidance
6. IECEx Technical Capability Documents (TCD)
7. ExTAG decision sheets (DSs)

NOTE The latest editions of the above documents were applied.

## ExTL persons interviewed

|  |  |
| --- | --- |
| **Name** | **Position** |
| Slobodon Sertić | Head of Laboratory |
| Stipo Đerek | Senior Assessor |
| Marko Ruzic | Lead Auditor for IECEx |
| Ana Hađak | Certification engineer |
| Ivan Stepanić | Certification engineer |
| Rikard Slunjski | Certification engineer |

## Associated ExCB(s)

The ExTL is integral with the ExCB

## Organisation

### Names, titles and experience of the senior executives

| **Name** | **Title** | **Experience** |
| --- | --- | --- |
| Stipo Đerek | Director of Sector for Certification and Testing | 24 years in Ex |
| Slobodon Sertić | Head of Laboratory | 34 years in Ex |

### Name, title and experience of the quality management representative

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Experience**  |
| Marko Ružić | Quality Manager | 14 years  |

### Other employees in ExTL activity

| **Name** | **Title/responsibility** | **Experience in Ex and Ex h** |
| --- | --- | --- |
| There are several employees who are able to act in the testing Function |

## Organizational structure

See Annex A

## Resources

While covered during the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV, staff were interviewed and found to demonstrate competence and understanding for assessment and test against IEC 60079-28.

## Test reports issued

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## National accreditation

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

Application for National accreditation for standard involved in this scope extension has been made. The next surveillance will include IEC 60079-28. Due to the fact it is not today included annual IECEx surveillance is required

## Calibration

Not relevant as this is a scope extension assessment. This was covered in the reassessment visit carried out on 13/15 June 2016, ExMC/1195/DV.

## Proficiency

Ex-Agencija partakes in the Proficiency testing organised by PTB at this point in time no issues raised concerning participation in the PTP.

## Comments (including issues found during assessment)

Minor issues were found which were cleared to the satisfaction of the assessment team during the visit (see 3.17).

Annex A

Organisation Chart

