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

**TITLE: IECEx Assessment Report for the acceptance of Fiditas d.o.o., Croatia, to become an Accepted Ex Certification Body, ExCB, within the IECEx Equipment Scheme, 02.**

**Circulation to: Members of the IECEx Management Committee, ExMC**

**INTRODUCTION**

Members may be aware of the closure of Ex-Agencija, HR, and the transfer of their certification activities to Fiditas of Croatia.  While it is noted that many of the staff moved from Ex-Agencija to Fiditias, the Secretariat organised a special application assessment of Fiditias to review the change and ensure that Fiditas were in a position to take over the role of ExCB in the IECEx 02 Certified Equipment Scheme.

At this point in time Fiditas is to operate as an ExCB with DNV GL Presafe as their associated ExTL.

This document provides a report of the IECEx assessment of Fiditas and is issued for voting by ExMC.

***This document is hereby submitted for ExMC approval via correspondence using the IECEx on-line voting system.  ExMC Members are requested to submit their vote via the IECEx On-line*** [***Ballot System***](https://www.iecex.com/ballot) ***by the closing date 2020 01 24***

***Please refer to OD 050 for guidance on the “IECEx On-line voting system.”***

***Chris Agius***

**IECEx Secretariat**

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

Fiditas d.o.o.

Karlovačka cesta 197

10250 Zagreb-Lučko

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

Fiditas d.o.o. as ExCB

The main purpose of this assessment was due to changes in Croatia with Fiditas taking over the role of ExCB from the former Ex Agencija including the on-going maintenance of IECEx certificates previously issued by Ex Agencija which will become the responsibility of Fiditas

### Name and title of nominated principal contact

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **E-mail address** |
| Mr Marino Kelava | Head of Certification Department | [marino.kelava@fiditas.com](mailto:marino.kelava@fiditas.com) |

## Assessment information

### Members of the assessment team

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

### Place(s) of assessment

Karlovačka cesta 197  
10250 Zagreb-Lučko   
CROATIA

### Assessment date(s)

11 November 2019 – onsite plus pre and post site visit assessments

## Scope

### ExCB scope for equipment certification scheme

| **Number** | **Title** | **Scope** |
| --- | --- | --- |
| IEC 60079-0  Ed. 5, Ed. 6 Ed. 7 | Explosive atmospheres - Part 0: Equipment - General requirements | Requested |
| IEC 60079-1  Ed. 6, Ed. 7 | Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures “d” | Requested |
| IEC 60079-2  Ed. 5, Ed. 5 Ed. 6 | Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure «p» | Requested |
| IEC 60079-5  Ed. 2, Ed. 3, Ed. 4 | Explosive atmospheres - Part 5: Equipment protection by powder filling «q» | Requested |
| IEC 60079-6  Ed. 2, Ed. 3, Ed. 4 | Explosive atmospheres - Part 6: Equipment protection by oil immersion «o» | Requested |
| IEC 60079-7  Ed. 4, Ed. 5, Ed. 5.1 | Explosive atmospheres - Part 7: Equipment protection by increased safety "e" | Requested |
| IEC 60079-11  Ed. 5, Ed. 6 | Explosive atmospheres - Part 11: Equipment protection by intrinsic safety “i” | Requested |
| IEC 60079-13 Ed. 1, Ed. 2 | Explosive atmospheres - Part 13: Equipment protection by pressurized room 'p' | Requested |
| IEC 60079-15  Ed. 3, Ed. 4, Ed. 5 | Explosive atmospheres - Part 15: Equipment protection by type of protection "n" | Requested |
| IEC 60079-18  Ed. 2, Ed. 3, Ed. 4 | Explosive atmospheres - Part 18: Equipment protection by encapsulation “m” | Requested |
| IEC 60079-25  Ed. 1, Ed. 2 | Explosive atmospheres - Part 25: Intrinsically safe electrical systems | Requested |
| IEC 60079-26  Ed. 1, Ed. 2, Ed. 3 | Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga | Requested |
| \*IEC 60079-27  Ed. 1, Ed. 2 | Explosive atmospheres - Part 27: Fieldbus intrinsically safe concept (FISCO) | Requested |
| IEC 60079-28  Ed. 1, Ed. 2 | Explosive atmospheres - Part 28: Protection of equipment and transmission systems using optical radiation | Requested |
| IEC 60079-30-1  Ed. 1 | Explosive atmospheres -Part 30-1: Electrical resistance trace heating - General and testing requirements | Requested |
| IEC 60079-31 Ed. 2 | Explosive atmospheres - Part 31: Equipment dust ignition protection by enclosure "t" | Requested |
| IEC TS 60079-46 Ed.1.0 | Explosive atmospheres - Part 46: Equipment assemblies | Requested |
| ISO 80079-36  Ed. 1 | Explosive atmospheres - Part 36: Non-electrical equipment for explosive atmospheres – Basic method and requirements | Requested |
| ISO 80079-37  Ed. 1 | 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" | Requested |
|  |  |  |
| DS 2015/001A | IECEx Assessment and Certification of Equipment assemblies | Requested |

NOTE 1 Standards shown with an asterisk (\*) are superseded standards

NOTE 2 Unless otherwise indicated, earlier editions of standards (even if with a different number) are considered to be covered in the above scope for the purposes of the assessment.

NOTE 3 The above list highlights any extension of scope in the list above for new standards or later editions of standards Requested scope.

### ExTL scope

Fiditas is applying as an ExCB associated with DNV GL Presafe as their associated ExTL. Therefor the ExTL scope is that of DNV GL Presafe.

On 2019-10-04, DNV GL confirmed that it will be the ExTL to Fitidas. The agreement was signed on 2019-11-11. It was reviewed during the assessment and was found meet IECEx rules.

### ExCB scope for Service Facilities Scheme

Service Facilities Scheme is not in the scope of Fiditas

### ExCB scope for ExMark Scheme

The ExMark scheme is not in the scope of Fiditas for the moment. However, Fiditas understood that there is an evolution within the scope of the IECEx Mark and is ready to sign the IECEx Mark License with IEC to be able to deliver the mark to its clients.

# Common information

## Legal entity of body

Fiditas d.o.o. is a registered company under number MBS 081018714 since March 8, 2016. It was updated in December 14, 2017 in order to include the four Managing Partners: Josip Deskin, Berislav Prpic, Mario Mackovic and Marino Kelava.

The last update was July 12, 2018 for the change of address.

The document was checked during the assessment and found to meet the requirements of the IECEx.

## Financial support

Under the Fiditas financial policies, the testing and certification activities of Fiditas are required to be run on a self-financing basis from the fees charged for their services.

## History

Fiditas d.o.o. is a private company founded in March 8, 2016.

Today there is 10 people working at Fiditas. Most of them are coming from Ex-Agencija which was a recognised ExCB and ExTL. In 2018, the Croatian Authority decided to close the certification activities of Ex-Agencija.

In the beginning of 2019, the Croatian Authority confirms that Fiditas can be a Certification Body and take over the surveillance audits for all formerly issued ATEX and IECEx certificates issued by Ex Agencija.

In April 2019 Fiditas was assessed by the Croatian Accreditation Agency and issued the Accreditation certificate according ISO/IEC 17065:2012 on 2019-07-23 for the certification of:

* Ex equipment and protective system
* Explosives for civil use
* Pyrotechnic articles

On September 20, 2019 Fiditas was notified to European Commission by the Croatian Authority and register under the number: 2829.

## Documentation

### Quality manual

The Quality Manual consists of Business principles, Sales, Human resources, HSE, Finance, Generic, Marketing and Subcontracting, Laboratory Management, Quality improvement, Impartiality and Legal.

There is also a specific Quality Manual for the certification activities.

The whole QM is complete and accessible by all employees on the intranet. The QM was checked during the assessment and found to meet the requirements of the IECEx.

### Procedures

Fiditas has a comprehensive range of procedures covering all aspects of the testing operations and were audited as part of this assessment. Where applicable each procedure has with it an associated test sheet for completion by the staff. The relevant existing procedures were found to meet the requirements of the IECEx.

IECEx Procedure POS-C-15 covers IECEx activities and was reviewed and found to meet IECEx requirements.

### Work instructions

Fiditas has comprehensive ranges of work instructions detailing the general procedure and sets out in WI documents.

These work procedures and work instruction are readily available to all staff on intranet and digital server.

### Records (including test records where relevant)

All records are appropriately maintained and stored. There is also an archiving process in place for all records. The system was found to meet the requirements of the IECEx. The records retained are a combination of hard copy records and electronic records, with the assessment team confirming appropriate control procedures and confirmation of records retained.

The assessment team also confirmed that retention of records complied with IECEx requirements including the disposition of records.

### Document change control

Fiditas has procedure relating document change control in document POS-O-01. The assessment team confirmed that this also addressed the issue of externally generated documents, eg standards, IECEx ODs and also ExTAG Decision sheets.

## Confidentiality

All employees and members of committee sign confidentiality agreements when they start to work for Fiditas. Examples of these were sighted by the team and found to meet the requirements of the IECEx.

There is a system of security control at the entrance gate of each building including door keys.

## Publications (Hard cover and Electronic)

IECEx scheme rules for Fiditas Ex certification and application forms are available on their website.

## Recognition and agreements

Fiditas have recognition by the Croatian Accreditation Body regarding ISO/IEC 17065.

## Internal audit and periodic management review

There is an overall audit system for Fiditas, the last audit was performed on 23.4.2019.

The management review meeting that took place on 25.4.2019 was reviewed. It includes, and covers, internal audits, corrective actions/accreditation audits, customer satisfaction (including complaints).

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

Today Fiditas subcontract all tests and assessment to its associated ExTL: DNV GL Presafe.

## Training and competence

All staff employed are selected for qualifications and/or experience relevant to their responsibilities.

On a regular basis there is training of people in the ExCB on the operations, outcome of audits, revised standards.

There is a competency matrix for each member of the ExCB. Training of personnel is performed regularly and described in QMCert, Clause 6.1.2.1. This was found to meet IECEx Requirements.

## Complaints and appeals (including appeals to IECEx)

There is a general process in Fiditas for internal complaints, internal and external audits, and external complaints. This covers the complaints mechanism requirements of the ExCB.

In the Ex Products Certification procedure TU-CERT-ATEX-e rev 3, there is special clauses (7.) to ensure that complaints regarding certified products. Also, to ensure that appeals and disputes in respect of certification activity and dealt with fairly and transparently. The procedures address the provision of appeals to IECEx and the applicants are advised of this facility.

## 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

## Recommendations

Based on the assessment performed on 11 November 2019, Fiditas is recommended for acceptance as ExCB in the IECEx Certified Equipment Scheme

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

Date: 2019-11-18

# ExCB for IECEx Certified Equipment Scheme

## Assessment references

1. IECEx02 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
2. OD003-2 Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
3. ISO/IEC 80079-34 Edition 1, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture
4. OD009 Issuing of CoCs, ExTRs and QARs
5. 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
6. OD0026 IECEx Certified Equipment Scheme – Guidelines for the qualification of Lead Auditor and Auditors, in accordance with the IECEx System
7. ISO/IEC 17065, General requirements for bodies operating product certification systems
8. IECEx Document OD17 Drawing and documentation guidance
9. IECEx Technical Capability Documents (TCD)
10. ExTAG decision sheets (DSs)

NOTE The latest editions of the above documents were applied

## ExCB persons interviewed

|  |  |
| --- | --- |
| **Name** | **Position** |
| Marino Kelava | Head of Certification Department &  Managing Partner |
| Stipo Đerek | ATEX & IECEx Senior Expert |
| Mario Mackovic | Managing Partner |

## Associated ExTL(s)

The laboratory for IECEx testing is:

* DNV GL Presafe AS, Veritasveien 3,1363 Høvik, NORWAY.

A formal agreement was signed on 11 November 2019.

## Associated certification functions

Fiditas provides ATEX certificates in accordance with ATEX Directive 2014/34/EU and their operations are accredited to IEC/ISO 17065 by the Croatian Accreditation Body.

Fiditas is a Notified Body according to the ATEX directive 2014/34/EU. Their Notified Body number is 2829.

## National marks and certificates

Fiditas is an ATEX Notified Body their ATEX certificates are accepted by the European commission and by European state regulators.

## Standards accepted

See clause 1.5 of this report

## National differences to IEC standards

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

## Organisation

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

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Experience in Ex field** |
| Marino Kelava | Head of Certification Department & Managing Partner | > 19 years |
| Stipo Đerek | ATEX & IECEx Senior Expert | > 25 years |
| Mario Mačković | Managing Partner | > 16 years |

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

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Experience** |
| Mario Macković | Quality Manager | > 16 years |

### Name and title of signatories for certification

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Comments** |
| Marino Kelava | Head of Certification Department & Managing Partner |  |
| Stipo Đerek | ATEX & IECEx Senior Expert |  |

### Other employees in ExCB activity

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Responsibility and Experience in Ex** |
| Marino Kelava | Head of Certification Department & Managing Partner | > 19 years |
| Mario Mačković | Managing Partner | > 16 years |
| Stipo Đerek | ATEX & IECEx Senior Expert | > 25 years |
| Marco Ghisu (external) | External QAR assessor | > 10 years |

## Organizational structure

See Annex A

## Administration

### Administrative structure

Sufficient administrative assistance is provided

### Indemnity insurance

Fiditas holds professional indemnity and public liability insurance. These are covered in one policy from 01 June 2019 which was reviewed, and its validity was found to be extended every year. The cover is worldwide and Ex certification which means that IECEx certification is included.

## Resources

Fiditas has an adequate number of staff for the current level of business. They are experienced in Ex activities.

The laboratory and offices are located in an industrial unit which provides an adequate environment for the work.

It is noted that the laboratory does not perform for the moment any Ex testing.

## Committees (such as governing or advisory boards)

The composition and terms of reference of the Certification Impartiality Committee are given in the Quality Manual. The Ex Committee comprises representatives of manufacturers and users interests with no single interest predominating. The content of the procedures meets the requirements of ISO/IEC 17065 and the IECEx requirements.

## Certification operations

### National approval/certification methods

Fiditas is recognised under the National accreditation systems and schemes. It has procedures for compliance with IECEx Rules and Operational Documents. Fiditas is a Notified Body, No. 2829 regarding ATEX Directive 2014/34/EU.

### Certification policy

The Quality Manual is available and contains a quality policy which is generic, and which allows for Fiditas to provide services regarding Ex equipment. Further aspects related to the certification policy are covered in the general quality policy and were seen to be in conformity with the requirements of ISO/IEC 17065 and IECEx 02.

### Application for certification

The complete certification process for delivering certificates is contained in Quality Manual, Procedure POS-C-15 and Application form OBR-C-1-04 which is provided to customers by the staff, by email and is also available on web pages. The procedures were found by the assessment team to meet the requirements of IECEx.

### Certification decision

The certification decision is taken by one of the two Certification Decision Managers. In their absence no other personnel is able to take that decision.

The above is documented in the Certification Manual QMCert which includes the Competency Matrix (document OD-O-02) for ExCB in CROATIA.

### Suspension and cancellation of certificates

The suspension of certificates rules is well defined in Certification Manual QMCERT and technical instruction TU-CERT-ATEX-e and there is specific reference as to how this relates to the IECEx System.

## Certificates issued

Number of certificates issued under for the preceding four years for each type of protection as ATEX Notified Body only.

|  |  |  |  |
| --- | --- | --- | --- |
| **Standard numbers** | **Type of protection or other identifying information** | **Number of issued certificates (for last 4 years)** | |
|  |  | **2019** |
| IEC 60079-0 | General Requirements | 22 |
| IEC 60079-1 | Flameproof enclosures | 12 |
| IEC 60079-2 | Pressurised Enclosures | - |
| IEC 60079-7 | Increased Safety | 17 |
| IEC 60079-11 | Intrinsic Safety | 3 |
| IEC 60079-15 | Type of protection n | - |
| IEC 60079-18 | Encapsulation m | 6 |
| IEC 60079-25 | Intrinsic safety systems | - |
| IEC 60079-28 | Optical protection | 1 |
| IEC 60079-31 | Protection by enclosure t | 1 |

While not having issued certificates for IEC TS 60079-46, ISO 80079-36, -37 since September, Fiditas staff did demonstrate sufficient knowledge and understanding of the Ex techniques and philosophy behind these standards as an ExCB, noting these standards are within the scope of their associated ExTL.

## National accreditation

Fiditas has Croatian Accreditation to ISO/IEC 17065 as a certification body. The certificate number is 3635 is valid until July 2024 and a copy is shown at Annex B of this report. The link to the Croatian Accreditation Agency website is:

* [www.akreditacija.hr/registry](http://www.akreditacija.hr/registry) Keyword: FIDITAS

The scope of this accreditation includes the national scheme for Ex Certificate which compliance to the ATEX Directive 2014/34/EU. The scope is available online on the same link and can be shown in [www.akreditacija.hr/registry](http://www.akreditacija.hr/registry) Keyword: FIDITAS.

## Assessment of manufacturers and issue of QARs

POS-C-02 Procedure addresses assessments of manufacturers. Technical instruction TU-PR\_ATEX Ed2 is also available for manufacturers on Fiditas web sites. The report format includes all the requirements from the IECEx Scheme together with ATEX requirements.

For IECEx certification schemes a set of documented procedures is in place to enable surveillance to be carried out in accordance with the criteria of the certification systems. The requirements for manufacturing surveillance activities (including initial and ongoing inspection of product during manufacture, audit of quality system and audit of products) are detailed within the relevant scheme rules and in relevant procedures.

## Comments (including issues found during assessment)

Minor issues were found which were cleared to the satisfaction of the assessment team after the assessment.

These included:

* The final agreement with DNV Presafe was shown during the assessment and signed before the end of the day

# ExTL for IECEx Certified Equipment Scheme

Today Fiditas is not and ExTL. And has only applied to become an IECEx Accepted ExCB at this time.

# Annexes

Annex A - Overall Organisation Chart

Annex B - Accreditation Certificate for ISO/IEC 17065

Annex C - Scope of 17065 Accreditation

1. Overall Organisation Chart

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | | |  | | **MANAGEMENT** | | | | | |  | | |  | | |  | | |
|  | |  | | |  | | | | |  | |  | | | |  | | |  | | |
|  | |  | | |  | | | | |  | |  | | | **Impartiality Committee** | | | | |  | |
|  | |  | | |  | | | | |  | |  | | |  | |
|  | |  | | |  | | | | |  | |  | | | |  | | |  | | |
|  |  | | | |  |  | | | | | |  | |  | | | | | | |  |
| **Laboratory for explosion protection** | | |  | **Certification department** | | | | |  | | **Industry**  **department** | | | | | |  | **Department for trainings** | | | |
|  | |  | | |  | | |  | | | |  | | | |  | | |  | | |

1. Accreditation Certificate for ISO/IEC 17065



1. Scope of 17065 Accreditation



