

**INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) SCHEME  
FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR  
USE IN EXPLOSIVE ATMOSPHERES  
(IECEX SCHEME)**

**Circulated to: Ex Management Committee, ExMC**

**TITLE: IECEx Assessment Report for the acceptance of *ZELM Explosionsschutz GmbH* as an accepted IECEx Certification Body (ExCB)**

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**INTRODUCTION**

This document contains the IECEx Assessment Report for the acceptance of *ZELM Explosionsschutz GmbH* as an IECEx Certification Body (ExCB) within the IECEx Scheme.

The report is hereby submitted for voting.

Please consider the assessment report which is issued for final vote by **2008 05 12**

**Chris Agius**  
IECEX Secretariat

Address:  
IECEX Secretariat  
SA Building  
286 Sussex Street  
Sydney 2000  
Australia

Tel: +61 2 8206 6940  
Fax: +61 2 8206 6272  
Email: [chris.agius@iecex.com](mailto:chris.agius@iecex.com)  
Internet: [www.iecex.com](http://www.iecex.com)

# IECEX ASSESSMENT REPORT FOR ZELM ExCB (IECEX Certification Body)

## Type of Assessment:

- Initial Assessment for Candidate ExCB X

## 1. OBJECT AND FIELD OF APPLICATION

### 1.1. Country:

Germany

### 1.2. Name of Candidate ExCB

ZELM Explosionsschutz GmbH

### 1.3. Members of the Assessment Team

Jim Munro – Chairman Panel of Assessors – Lead IECEx Assessor

Heinz Berger – IECEx Officer, IECEx Lead Assessor

Theo Pijpker- KEMA, IECEx Assessor

### 1.4. Place and Date of Assessment

Siekgraben 56, D-38124

Braunschweig, Germany

29-31 August 2007

### 1.5. Assessment References

- i) IECEx 02 Third Edition 2006-11 IECEx Scheme rules of procedure
- ii) IECEx OD 003/V1 IECEx Assessment procedures
- iii) IECEx OD 005/V2 Quality System requirements for manufacturers
- iv) IECEx OD 009/V1 Issuing of CoCs, ExTRs and QARs
- v) IECEx Documents OD025/V1 and ExMC/161/CD Management of assessment and surveillance programs for manufacturers (includes QAR forms)
- vi) ISO/IEC Guide 65:1996
- vii) IECEx Document OD 017/V3 Drawing and documentation guidance
- viii) ExCB application documents dated 25 April 2007

### 1.6. Scope of Application

Number	Title
60079-0	Electrical apparatus for explosive gas atmospheres Part 0: General requirements

<u>60079-1</u>	Electrical apparatus for explosive gas atmospheres Part 1: Construction and verification test of flameproof enclosures of electrical apparatus
<u>60079-2</u>	Electrical apparatus for explosive gas atmospheres Part 2: Electrical apparatus, type of protection 'p' (Pressurization)
<u>60079-5</u>	Electrical apparatus for explosive gas atmospheres Part 5: Powder filling "q"
<u>60079-6</u>	Electrical apparatus for explosive gas atmospheres Part 6: Oil-immersion 'o'
<u>60079-7</u>	Explosive atmospheres Part 7: Equipment protection by increased safety "e"
<u>60079-11</u>	Electrical apparatus for explosive gas atmospheres Part 11: Intrinsic safety 'i'
<u>60079-15</u>	Electrical apparatus for explosive gas atmospheres Part 15: Electrical apparatus with type of protection 'n' (Non-Sparking)
<u>60079-18</u>	Electrical apparatus for explosive gas atmospheres Part 18: Encapsulation 'm'
<u>60079-25</u>	Electrical apparatus for explosive gas atmospheres Part 25: Intrinsically safe systems
<u>60079-26</u>	Explosive atmospheres Part 26: Equipment with equipment protection level (EPL) Ga
<u>60079-27</u>	Electrical apparatus for explosive gas atmospheres Part 27: Fieldbus intrinsically safe concept (FISCO) and Fieldbus non-incendive concept (FNICO)
<u>60079-28</u>	Explosive atmospheres Part 28: Protection of equipment and transmissions systems using optical radiation. <b>Scope restricted to inherently safe optical radiation "op is"</b>
<u>61241-0</u>	Electrical apparatus for use in the presence of combustible dust Part 0: General requirements
<u>61241-1</u>	Electrical apparatus for use in the presence of combustible dust Part 1: Electrical apparatus protected by enclosures
<u>61241-4</u>	Electrical apparatus for use in the presence of combustible dust Part 4: Type of protection 'pD'
<u>61241-18</u>	Electrical apparatus for use in the presence of combustible dust Part 18: Protection by encapsulation 'mD'
<u>62086-1</u>	Electrical apparatus for explosive gas atmospheres - Electrical resistance trace heating - Part 1: General and testing requirements

**1.7. Candidate ExCB Persons Interviewed**

<b>Name</b>	<b>Position</b>
Harald Zelm	CEO
Thomas Zelm	CEO

**1.8. Legal Entity of the Candidate ExCB**

ZELM Explosionsschutz GmbH is a registered company under number HRB 9963 since April 20, 2005. Prior to this date ZELM Ex e.K. was active as a sole proprietorship.

**1.9. Associated Testing Laboratories**

The ExTL is integral with ExCB at the same site.

**1.10. Associated Certification Functions**

ZELM Explosionsschutz GmbH is a Notified Body according to the ATEX directive 94/9/EC since 1998.

**1.11. National Marks and Certificates**

There are no national Marks and Certificates issued.

**1.12. Financial Support**

There is no financial support. ZELM Explosionsschutz GmbH is self-funded from certification, testing and quality assessment activities.

**1.13. History**

In 1993 the company was founded as a consultancy company to help their customers obtain certification with other bodies.

In the year 1997 the operation changed its direction to set itself up as a certification and testing body

Since the 2<sup>nd</sup> of December 1998 ZELM has been accredited by the ZLS as a European Notified Body according EN45001 and 45011 with Notified Body number 0820. They produce test reports and issue EC-Type-Certificates of Conformity in every type of protection which are valid throughout Europe. In addition ZELM has accreditation according EN45012 and is able to issue certificates for quality systems based on the EN13980.

Since August 1999 ZELM has had an agreement with Factory Mutual (FM) in the USA. This agreement covers the complete test laboratory and allows them to make tests needed for the North American market. Test reports are exchanged to facilitate the issuing of certificates.

**1.14. Standards Accepted**

See clause 1.6 of this report

### 1.15. *National Differences to IEC Standards*

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

## 2. ORGANISATION

### 2.1. *Names, Titles and Experience of the Senior Executives*

Name	Title	Experience In Ex
Harald Zelm	Dipl.- Ing.	24 years
Adolf Gruber	Engineer	44 years

### 2.2. *Name, Title and Experience of the Quality Management Representative*

Name	Title	Experience in Ex
Thomas Zelm	Auditor (TGA/EOQ)	8 years

### 2.3. *Name and Title of Nominated Principal Contact*

Name	Title	Comments
Thomas Zelm	Auditor (TGA/EOQ)	<a href="mailto:tzelm@zelm.de">tzelm@zelm.de</a>

### 2.4. *Name and Title of Signatories for Certification*

Name	Title	Comments
Harald Zelm	Dipl.- Ing.	
Adolf Gruber	Engineer	

### 2.5. *Other Employees in ExCB activity*

Name	Title	Responsibility
Henning Richter	Dr.	QAR
Thomas Zelm	Auditor (TGA/EOQ)	QAR
Waltraud Zelm		Certification Administration
Edward Brzostek	Dr.-Ing.	Training, Standards, Committees
Walpurga Kraatz		Archive

See Annex 1 for the organization chart of the ExCB including the Quality Audit Body.

The CVs of personnel involved in IECEx certification activities were checked and found to be acceptable, possessing the necessary qualifications, experience and competence to undertake the IECEx certification activities.

### 2.6. *Administration*

Certification administration is organized in order to handle all documentation and correspondence with view to certification activities. 1 ½ positions are related to this activities.

## **2.7. Indemnity Insurance**

ZELM presented a current insurance contract issued by the „Öffentliche Versicherung Braunschweig“, carrying the number 494149 01/73.

## **3. RESOURCES**

A total of ten (10) employees are involved in certification activities which includes administration, certificate release, manufacturer auditing, general handling, customer service, accreditations, trainings, etc., As part of the ZELM management system, resources are allocated according to the required skills and knowledge, as reflected in the ZELM Competency Matrix. The matrix and training records were successfully reviewed during the assessment.

## **4. COMMITTEES / Governing Board / Appeals / Advisory Board**

At the time of the assessment there was not committee appointed with duties related to the certification. Subsequently an advisory board was formed consisting of three persons thereby meeting the requirements of ISO/IEC Guide 65.

## **5. CERTIFICATION OPERATIONS**

### ***5.1. National Approval/Certification Methods***

ZELM operates according to the European conformity assessment procedures for Ex, the ATEX directive 94/9/EC.

### ***5.2. Certification Policy***

The IECEx certification procedure is described in the quality handbook chapters 22 and 23 which is based on document IECEx OD 009. The detailed certification instructions are described in clause 4 of the QM.

### ***5.3 Application for Certification***

ZELM has developed a certification application form also covering IECEx.

### ***5.4 Withdrawal and Cancellation of Certificates***

The withdrawal and cancellation process is described in the QM in chapter 4, clause 5.

### ***5.5 Independent Certification Review/Decision***

As required by ISO/IEC Guide 65 (Item 4.2 (f) Zelm Quality Document “Declaration of Exclusiveness” 12.06.07 ensures that this requirement is met.

## **6. STATISTICS**

### **6.1 Certificates Issued**

Number of certificates issued under the ATEX, national or regional schemes in the preceding four years for each type of protection:

**Note:** The numbers listed below indicate the certification of one protection type. However, more than one protection type can be certified on the same certificate.

Standards	Number of Ex certificates issued				
	2003	2004	2005	2006	
<b>Gas atmosphere</b>					
IEC 60079-0/ EN 50014					part 0 included in below numbers
IEC 60079-1/ EN 50018	9	7	15	12	43
IEC 60079-2 / EN 50016	0	0	0	0	0
IEC 60079-5/ EN 50017	2	2	1	1	6
IEC 60079-6/ EN 50015	0	0	0	0	0
IEC 60079-7/ EN 50019	6	9	11	7	33
IEC 60079-11/ EN 50020	31	24	49	43	147
IEC 60079-15/ EN 50021	5	3	7	9	24
IEC 60079-18 / EN 50028	7	4	8	8	27
IEC 60079-25/ EN 50039	0	0	0	0	0
IEC 60079-26/ EN 50284	0	0	1	1	2
IEC 60079-27	0	0	0	0	0
<b>Combustible dust</b>					
IEC 61241-0					part 0 included in below numbers
IEC 61241-1	0	0	1	4	5
IEC 61241-1-1/ EN 50281-1-1	15	14	25	15	69
IEC 61241-4	0	0	0	1	1
IEC 61241-11	5	2	2	5	14
IEC 61241-18	0	0	0	0	0

## 7. DOCUMENTATION

### 7.1 Quality Manual

There is a comprehensive quality manual that defines how the body operates. This incorporates details on how ZELM will operate within the IECEx Scheme and the scope of standards to be covered.

### 7.2 Procedures

There is a range of procedures covering to operation in more detail and are described in Chapter 23 of the QM.

### 7.3 Work Instructions

Staff work instructions are described in the QM under Chapters 22 and 23.

### 7.4 Records

All certificates issued by ZELM are shown on the Internet under [www.zelm-ex.com](http://www.zelm-ex.com). The IECEx Certificates will be shown on the IECEx Homepage.

#### **7.5 Document Change Control**

Document change control is described in the QM chapter 5, Clause 5.2.4. Document control is handled by the Quality Manager as the sole owner of the change control password.

### **8. CONFIDENTIALITY**

The confidentiality issue is described in QM chapter 1. The confidentiality declaration is signed by all employees and was viewed during the assessment. There is also a clause in the work contract covering the confidentiality issue.

### **9. PUBLICATIONS**

ZELM advises its services on the Internet under the URL [www.zelm-ex.de](http://www.zelm-ex.de).

### **10. NATIONAL ACCREDITATION**

ZELM holds accreditations for DIN EN 45011 (equivalent to ISO/IEC Guide 65) and DIN EN 45012 (equivalent to ISO/IEC Guide 62) from the German Accreditation Service ZLS and a Notification Certificate from the Federal Ministry of Labour and Social Affairs of Germany for the ATEX Directive 94/9/EG. The Notified Body number is 0820. The certificate concerning Guide 65 is valid until December 31<sup>st</sup>, 2008. The re-assessment of ZELM concerning ISO Guide 62 was performed in August 2006 without NCRs. However, ZELM is still waiting for the new documents but has a confirmation by ZLS by email that the old certificate is valid until replacement. See **Annexes 2 and 3** for the certificates. **Annex 4** shows the European Union certificate for the Notified Body carrying the number 0820.

### **11. RECOGNITION AND AGREEMENTS**

ZELM has a co-operation contract with Factory Mutual Research Corporation, Norwood, Massachusetts, USA. The scope of the agreement deals with the exchange of test reports concerning ENs and ANSI/ISA. The agreement was signed in August 1999 and is still valid.

### **12. INTERNAL AUDIT AND PERIODIC MANAGEMENT REVIEW**

The process for internal audits is described in QM chapter 17. All chapters of the QM are checked during a one year period. Management reviews are described in the QM in chapter 1, clause 1.8. and are performed once a year, usually at the end of November.

### **13. SUBCONTRACTING, USE OF OTHER LABS AND USE OF OTHER LOCATIONS**

Zelm has the capacity to perform nearly all tests according to the standards but some clauses are subcontracted as described below.



Resistance to light tests according to standard IEC 60079-0, clause 26.10 and IEC 61241-0, clause 23.4.7.5, are performed by "Atlas Material Testing Technology GmbH", 47228 Duisburg, Germany, Dr.-Alfred-Herrhausen-Allee 16. The laboratory holds an accreditation certificate for ISO/IEC 17025. The certificate is valid until November 2012. The signed subcontracting agreement was provided.

IEC 60079-15 Clauses 33.10, 33.11 and 33.12 are subcontracted to "Typentestzentrum Braunschweig Siemens AG", 38126 Braunschweig, Germany, Ackerstrasse 22. The laboratory holds a certificate for ISO/IEC 17025. The certificate is valid until May 2010. The signed subcontracting agreement was provided.

These tests are under the full control of ZELM according to the ZELM Procedure and as required by ISO/IEC Guide 65. This was confirmed by the assessment team during the visit.

## **14. TRAINING**

Training is described in QM chapter 18. Training is performed by ZELM employees having the relevant competences. A detailed record of training with the signatures of each participant was presented during the assessment. Auditors active in manufacturer assessments attend external seminars.

## **15. ASSESSMENT OF MANUFACTURERS AND ISSUE OF QARS**

Because they have not yet been able to issue IECEx QARs (initial IECEx assessment) the following ATEX Quality Reports were checked and found to be acceptable:

- # AB 0602001 (manufacturer located in Germany): with this QAR the protection technique "i" is covered;
- # AB 0702001 (manufacturer located in Germany): with this QAR the protection technique "d", "i", "e" and "m" are covered;
- # AB 0701001 (manufacturer located in Germany): with this QAR the protection techniques "i" is covered;
- # AB 0605001 (manufacturer located in Switzerland): with this QAR the protection techniques "d", "i" are covered;
- # AB 0706001 (manufacturer located in Germany): with this QAR the protection technique "d" and "e" are covered.

## **16. COMPLAINTS AND APPEALS (Including appeals to IECEx)**

Complaints and appeals are covered in Chapter 4 of the QM.

## **17. SPECIAL FACTS TO BE NOTED**

### ***17.1 Supporting Documentation***

Copies of additional supporting information for this assessment have been provided to the applicant and the IECEx Secretariat. These include:

- Details of issues raised and how these have been resolved
- Checklist for ISO/IEC Guide 65

## **18. COMMENTS (Including issues found during assessment)**

The only significant issues found during the assessment were the lack of an advisory board/certification committee for the ExCB, and the need to better define sub-contracting arrangements. These issues were subsequently resolved to the satisfaction of the assessment team.

New procedures introduced since the August 2007 site assessment now adequately address the issues as mentioned in 13 above

## **19. RECOMMENDATION**

Based on the initial assessment from 29 to 31 August 2007, the assessment team recommends acceptance of Zelm as an ExCB.

It is recommended that the scope of IEC 60079-28 be restricted to inherently safe optical radiation "op is".

Jim Munro  
Team Leader

Heinz Berger  
Expert Assessor

Theo Pijpker  
Expert Assessor

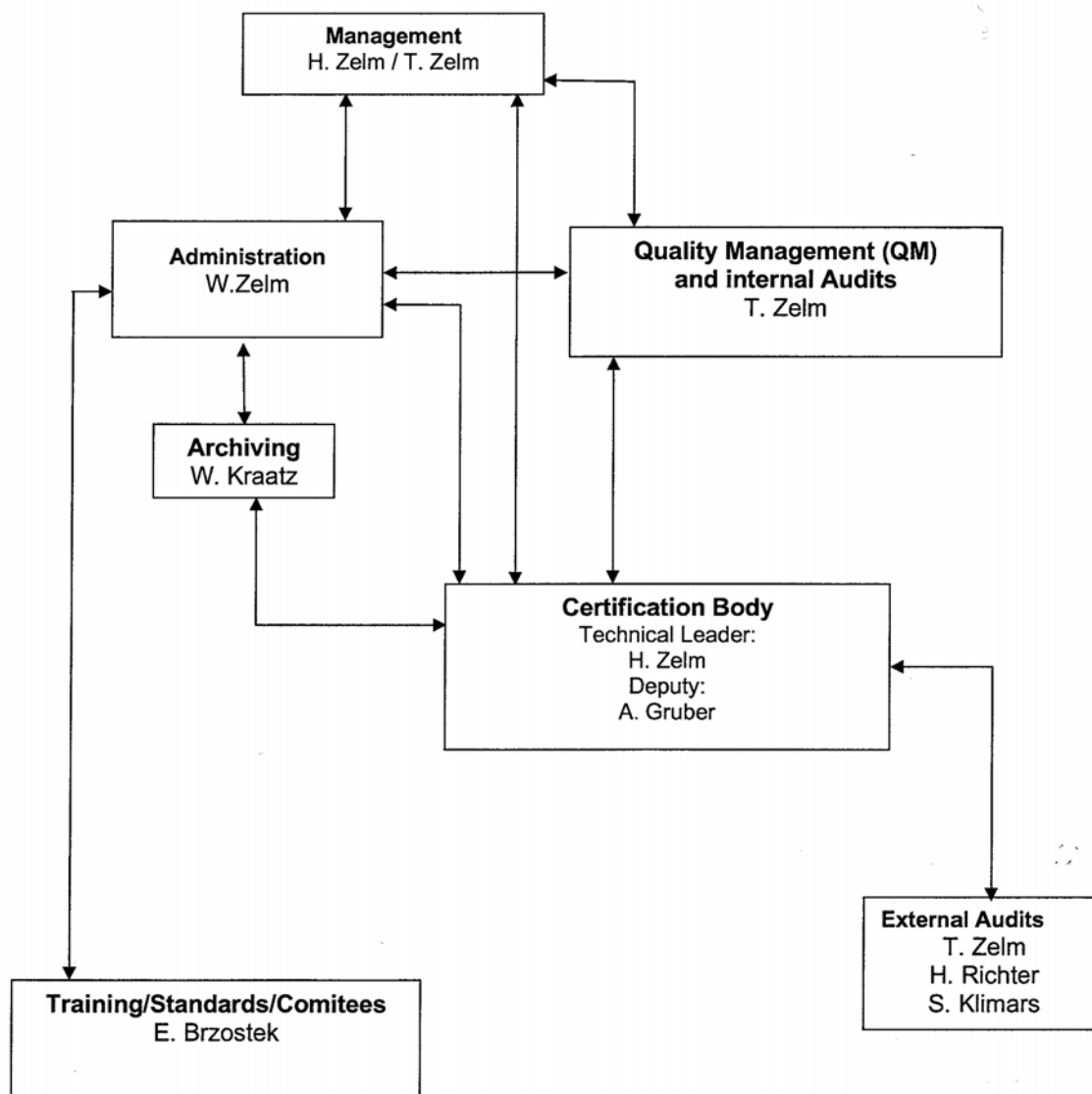
Date: 14 February 2008

**Independently reviewed by the IECEx Secretariat 2008 03 28**

## **List of Annexes:**

1. Organization Chart of ZELM ExCB
2. Accreditation Certificate for ISO/IEC Guide 65
3. Accreditation Certificate for ISO/IEC Guide 62
4. Notification Certificate as Notified Body 0820

# Annex 1 Organization Chart for ZELM ExCB



**Annex 2**  
**Accreditation Certificate for ISO/IEC Guide 65**

**AKKREDITIERUNG**



**Die Zentralstelle der Länder für Sicherheitstechnik (ZLS)**

bestätigt hiermit, dass die

**Prüf- und Zertifizierungsstelle ZelmEx**  
**Siekgraben 56, D-38124 Braunschweig**

die Anforderungen des § 11 Abs. 1 des Geräte- und Produktsicherheitsgesetzes


und der Norm DIN EN 45011 erfüllt und die Kompetenz besitzt,

**Geräte zur bestimmungsgemäßen Verwendung in**  
**explosionsgefährdeten Bereichen**

im Geltungsbereich des GPSG und der EG-Richtlinie 94/9/EG  
entsprechend den Bestimmungen des Akkreditierungsbescheides  
Nr. ZLS/3926-1/101/05  
**zu zertifizieren.**

Die Akkreditierung ist gültig bis zum 31.12.2008  
Reg.-Nr.: **ZLS-ZE-471/05**

München, den 07.03.2005

  
Dipl.-Wirtsch.-Ing. (FH) Huber  
Leiter der ZLS

ZLS im Bayerischen Staatsministerium für Umwelt, Gesundheit und Verbraucherschutz,  
Postfach 81 01 40, 81901 München



IECEx Secretariat



ExMC/427/DV  
March 2008

**Annex 3**  
**Accreditation Certificate for ISO/IEC Guide 62**

# AKKREDITIERUNG



**Die Zentralstelle der Länder für Sicherheitstechnik (ZLS)**

bestätigt hiermit, dass die

**Zertifizierungsstelle für QS-Systeme  
der  
Prüf- und Zertifizierungsstelle Zelm Ex  
Siekgraben 56, 38124 Braunschweig**

die Anforderungen des § 11 Abs. 1 des Geräte- und Produktsicherheitsgesetzes  
(GPSG)

und der Norm DIN EN 45012 erfüllt und die Kompetenz besitzt,

**Qualitätssicherungssysteme**

im Geltungsbereich des GPSG und der EG-Richtlinie 94/9/EG  
entsprechend den Bestimmungen des Akkreditierungsbescheides


Nr. ZLS-G3926.1-2005/2

**zu zertifizieren.**

Die Akkreditierung ist gültig bis zum **31.08.2012**.

Reg.-Nr.: **ZLS-ZQ-335/07**

München, den 05.09.2007

  
Dipl.-Wirtsch.-Ing. (FH) Huber  
Leiter der ZLS

ZLS im Bayerischen Staatsministerium für Umwelt, Gesundheit und Verbraucherschutz,  
Postfach 81 01 40, 81901 München



IECEx Secretariat



ExMC/427/DV  
March 2008

Annex 4  
Notification Certificate as Notified Body 0820

**The Federal Republic of Germany**

represented by the

**Federal Ministry of Labour  
and Social Affairs**

has notified

to the Commission of the European  
Community and  
the Member States of the European Union

the

**ZELM Ex**

**Prüf- und Zertifizierungsstelle**

Siekgraben 56

38124 Braunschweig

according to the Directive

**94/9/EC**

based on the official accreditation through the Central Authority  
of the Länder for Safety  
(Zentralstelle der Länder für Sicherheitstechnik)



Bonn, 2 August 2001

**EU identification number**

**0820**

  
Dirk Moritz