ExMC/1235/DV
July 2017

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

TITLE: IECEx Assessment Report for the acceptance of PRIMARA - Test und Zertifizier-GmbH, Germany, to participate as an Accepted Certification Body, ExCB, and an Accepted Test Laboratory, ExTL, in the IECEx System, Equipment Scheme, 02.

INTRODUCTION

This document contains the IECEx Assessment Report for the acceptance of PRIMARA - Test und Zertifizier-GmbH, Germany, to become an Accepted Certification Body, ExCB, and an Accepted Test Laboratory, ExTL, within the IECEx Equipment Scheme, 02.

Members are asked to note that PRIMARA is taking over the certification responsibilities of the former ExCB, ZELM.

The report is hereby submitted for voting by the ExMC.

Please consider the assessment report and return the completed voting form, a separate Word document, to the Secretariat by **2017 08 08.**

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

Chris Agius

IECEx Secretary

Visiting address:	**Contact Details:**
IECEx Secretariat **Level 33, Australia Square** **264 George Street** **Sydney NSW 2000** **Australia**	**Tel: +61 2 4628 4690** **Fax: +61 2 4627 5285** **E-mail: info@iecex.com** **http://www.iecex.com**

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

PRIMARA - Test und Zertifizier-GmbH

87600 KAUFBEUREN

GERMANY

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

CONTENTS

1 Assessment information

1.1 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

1.2 Type of assessment:

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

1.3 Details of body

1.3.1 Country

GERMANY

1.3.2 Name of body

PRIMARA - Test und Zertifizier-GmbH as ExCB and ExTL

1.3.3 Name and title of nominated principal contact

Name	Title	E-mail address
Mr Andreas Aufmuth	Certification Manager	andreas.aufmuth@primara.net

1.4 Assessment information

1.4.1 Members of the assessment team

Name	Role (modify as necessary)
Thierry Houeix (INERIS)	Lead assessor
Alexander Zalogin (NANIO CCVE)	Expert Assessor

1.4.2 Place(s) of assessment

Gewerbestraße 28
87600 KAUFBEUREN

1.4.3 Assessment date(s)

Initial site assessment visit = 13 - 15 December 2016

Follow up site assessment visit = 10 - 11 April 2017

1.5 Scope

1.5.1 ExCB scope for equipment certification scheme

Number	Title	Scope
IEC 60079-0 Ed. 6	Explosive atmospheres - Part 0: Equipment - General requirements	Requested
IEC 60079-1 Ed. 7	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures “d”	Requested
IEC 60079-2 Ed. 5	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"	Requested
IEC 60079-5 Ed. 3	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"	Requested
IEC 60079-6 Ed. 3	Explosive atmospheres - Part 6: Equipment protection by oil immersion "o"	Requested
IEC 60079-7 Ed. 4	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"	Requested
IEC 60079-11 Ed. 6	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety “i”	Requested
IEC 60079-15 Ed. 4	Explosive atmospheres - Part 15: Equipment protection by type of protection "n"	Requested
IEC 60079-18 Ed. 3	Explosive atmospheres - Part 18: Equipment protection by encapsulation “m”	Requested
IEC 60079-25 Ed. 2	Explosive atmospheres - Part 25: Intrinsically safe electrical systems	Requested
IEC 60079-26 Ed. 2	Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga	Requested
IEC 60079-28 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 60079-35-1	Explosive atmospheres - Part 35-1: Caplights for use in mines susceptible to firedamp - General requirements - Construction and testing in relation to the risk of explosion	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

1.5.2 ExTL scope

The ExTL scope is the same as for the ExCB.

1.5.3 ExCB scope for Service Facilities Scheme

Not in the scope of ExCB.

1.5.4 ExCB scope for ExMark Scheme

The ExMark scheme is not in the scope of PRIMARA.

2 Common information

2.1 Legal entity of body

PRIMARA - Test und Zertifizier-GmbH is a registered company under number HRB 10651 since July 20, 2010.

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

2.2 Financial support

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

2.3 History

PRIMARA - Test und Zertifizier-GmbH is a private company founded in May 2010. PRIMARA offers services regarding testing and certification for products and management system in the following field:

- Testing of electrical components and products regarding safety, usability and environmental compatibility against standards and European directives.
- Testing and certification of grid-protection according international guidelines and standards of grid-parallel operated generators, especially PV inverter
- Testing of active medical product in accordance with national and international standards, as well as Directive 93/42/EEC and MDA
- Testing and certification in accordance with Directive 2014/34/EU
- Audits, inspection and monitoring of factories according to ISO 17021
- Certification and Quality Assessments as ExCB within the IECEx 02 System with the exclusive ExTL ZELM Ex.

ZELM Ex e.K was previously located in Braunchweig and accepted as ExCB and ExTL. The company decided to move to Kaufbeuren. The laboratory of ZELM Ex was integrated fully into the Primara Testing Laboratory quality system. Thus, the ExTL is now Primara Test und Zertifizier-GmbH. The previous certification functions of ZELM are being taken over by Primara.

The Assessment Team included assessment of the merging of ZELM activities into Primara to ensure continuity and compliance with IECEx requirements.

2.4 Documentation

2.4.1 Quality manual

The Quality Manual consists of four levels:

- Level I - main part of the quality manual,
- Level II - the part with Standard Operating Procedures
- Level III - the part with work instructions and finally
- Level IV - the part with the form sheets.

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

2.4.2 Procedures

PRIMARA have 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.

2.4.3 Work instructions

PRIMARA have comprehensive ranges of work instructions detailing the general procedure, and sets out in WI documents.

2.4.4 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.

2.4.5 Document change control

PRIMARA have procedure relating document change control in document SOP-5.3-1. The assessment team confirmed that this also addressed the issue of externally generated documents, eg standards, IECEx ODs and also ExTAG Decision sheets.

2.5 Confidentiality

All employees and members of committees sign confidentiality agreements when they start to work for PRIMARA. 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 main entrance gate. In addition, the record is stored electronically are protected by Windows access and password.

2.6 Publications (Hard cover and Electronic)

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

2.7 Recognition and agreements

PRIMARA & the former ZELM Ex have recognition by DAkkS which is the German Accreditation Body regarding ISO 17025 and ISO 17065. Primara is currently extending its DAkkS scope according to the scope held by ZELM Ex. The Secretariat is to monitor this progress as delays in the process may trigger annual surveillance assessments by IECEx

2.8 Internal audit and periodic management review

There is an overall audit system for PRIMARA, including at technical level with the Ex operations. PRIMARA does have in place a method of regularly investigating existing testing activities.

Internal audits are done once a year for ExCB and ExTL activities. The internal audit for IECEx to ISO/IEC 17025 carried out on 14 October 2016 and ISO/IEC 17065 carried out on 16 and 17 February 2016 were reviewed. Findings raised and the corrective actions were viewed and found to be satisfactory. The audit took place over a complete day and had a team of two auditors. No nonconformities were found.

The management review meeting that took place on 17 December 2015 was reviewed. It includes covers internal audits, corrective actions/accreditation audits, customer satisfaction (including complaints).

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

PRIMARA subcontract some tests and they have a procedure for this and agreement with the External Company. The tests which are subcontracted are permitted by the IECEx TCD and listed in the TCD and are mainly:

- Small component ignition test,
- Resistance to light,
- Mechanical shock test for batteries,
- Continuous wave radiation.

Provision is also made for tests to be performed at the manufacturer's or user's facility in accordance with OD24. It was noted that the former ZELM had not used this feature.

2.10 Training and competence

All staff employed are selected for qualifications and/or experience relevant to their responsibilities. In chapter 6 of the ExCB manual, there is a table describing each member of staff also with a full job description, which comprehensively defines their responsibilities, job function, qualification requirements and their position within the organisation.

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

There is a competency matrix for ExCB and ExTL. This was found to meet IECEx Requirements.

2.11 Complaints and appeals (including appeals to IECEx)

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

In the Procedures SOP 5.6-1, there are special clauses to ensure that complaints regarding certified products, service, presentation of results, methods or any other subject are effectively dealt with. 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.

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:

- Details of issues raised and how these have been resolved
- Completed Technical Capability Document (TCD)

- Photos of the facilities/tests witnessed, included in the TCD
- Assessors' notes
- Tests witnessed:

60079-0 – IP66 test
60079-0 – Surface resistance test
60079-1 – Reference pressure
60079-1 – overpressure test
60079-1 – transmission test
60079-11 – spark ignition test
60079-11 – temperature rise on batteries
60079-18 – dielectric strength test
60079-31 – pressure test

In addition to the above, Primara staff demonstrated a thorough knowledge of the application of EN 13463 series of standards (ISO/IEC 80079 equivalent) with the assessment team noting their experience within the ATEX system.

2.13 Recommendations

Based on the assessment performed on Initial site assessment visit = 13 - 15 December 2016, and the follow up additional site assessment conducted on 10 - 11 April 2017 PRIMARA is recommended for acceptance in the IECEx scheme as an ExCB and ExTL in the IECEx Certified Equipment Scheme.

This is according to the scope of the standards listed in this document including the ISO 80079 36 and ISO 80079-37.

Thierry Houeix	Alexander Zalogin
Lead Assessor	Expert Assessor

Date: 13 June 2017

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) ISO/IEC 80079-34 Edition 1, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture

d) OD009 Issuing of CoCs, ExTRs and QARs

e) 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

f) OD0026 IECEx Certified Equipment Scheme – Guidelines for the qualification of Lead Auditor and Auditors, in accordance with the IECEx System

g) ISO/IEC 17065, General requirements for bodies operating product certification systems

h) IECEx Document OD17 Drawing and documentation guidance

i) IECEx Technical Capability Documents (TCD)

j) ExTAG decision sheets (DSs)

NOTE The latest editions of the above documents were applied

3.2 ExCB persons interviewed

Name	Position
Horst Haug	Certification Manager Deputy
Andreas Aufmuth	Certification Manager
Harald Zelm	Certification Review Engineer
Yilmaz Sezer	Project Engineer
Maximilian Pohl	Quality Manager
Valentin Haug	General Manager
Thorsten Germersdorf	Auditor

3.3 Associated ExTL(s)

The ExTL named ZELM Ex has been taken over by Primara and has been integrated into the PRIMARA quality system. The name of the ExTL therefore is now PRIMARA, it is now integral with the ExCB PRIMARA, with the appropriate procedures and systems in place to maintain independence.

The laboratories for IECEx testing is located at Gewerbestraße 28 , 87600 KAUFBEUREN, GERMANY.

3.4 Associated certification functions

PRIMARA provides ATEX certificates in accordance with ATEX Directive 2014/34/EU and their operations are accredited to IEC/ISO 17065 by the National Accrediting body DAkkS.

PRIMARA is a Notified Body according to the ATEX directive 2014/34/EU. Their Notified Body number is 2572.

3.5 National marks and certificates

PRIMARA is a new Notified Body. However, as an ATEX Notified Body their ATEX certificates are accepted by the European commission and by European state regulators.

3.6 Standards accepted

See clause 1.5 of this report

3.7 National differences to IEC standards

National differences to IEC standards are those 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 in Ex field
Horst Haug	Certification Manager Deputy	> 25 years
Andreas Aufmuth	Certification Manager	> 5 years
Valentin Haug	General Manager	> 5 years
Harald Zelm	Certification Review Engineer	> 35 years

3.8.2 Name, title and experience of the quality management representative

Name	Title	Experience
Maximilian Pohl	Quality Manager	> 5 years

3.8.3 Name and title of signatories for certification

Name	Title	Comments
Horst Haug	Certification Manager Deputy	
Andreas Aufmuth	Certification Manager	

3.8.4 Other employees in ExCB activity

Name	Title	Responsibility and Experience in Ex
Yilmaz Sezer	Project Engineer	> 10 years
Valentin Haug	General Manager	> 5 years
Thorsten Germersdorf	Auditor	> 5 years

3.9 Organizational structure

See Annex A

3.10 Administration

3.10.1 Administrative structure

Sufficient administrative assistance is provided

3.10.2 Indemnity insurance

PRIMARA holds professional indemnity and public liability insurance. These are covered in one policy from 08.12.2011 which was reviewed and its validity was found to be extended every year. The cover is considered acceptable.

3.11 Resources

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

The laboratory and offices are located in an industrial unit which provides an adequate environment for the work. The testing equipment is suitable for the range of tests carried out in house.

3.12 Committees (such as governing or advisory boards)

The composition and terms of reference of the Certification Governing Board are given in Quality Manual and SOP-9-4 documents. 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.

3.13 Certification operations

3.13.1 National approval/certification methods

PRIMARA is recognised under the National accreditation systems and schemes. It has procedures for compliance with IECEx Rules and Operational Documents. PRIMARA is a Notified Body, No. 2572 ATEX Directive 2014/34/EU

3.13.2 Certification policy

The Quality Manual is available in printed form. It contains a quality policy that makes reference to product certification. Further aspects related to 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

3.13.3 Application for certification

The complete certification process for delivering certificates is contained in Quality Manual and F7.2-1 Application Form provided to customers either by the website of PRIMARA or by the staff by email. The procedures were found by the assessment team to meet the requirements of IECEx.

3.13.4 Certification decision

In principle, the certification decision is taken by Horst Haug or A. Aufmuth, however systems are in place to deal with his absence.
The above is documented in the ExCB Competency Matrix.

3.13.5 Suspension and cancellation of certificates

The suspension of certificates rules is well defined in SOP-9-8 Document relating to IECEx Certification Program Manual Clause and there is specific reference as to how this relates to the IECEx System.

3.14 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)			
		2014	2015	2016	2017
IEC 60079-0	General Requirements			28	5
IEC 60079-1	Flameproof enclosures			8	1
IEC 60079-2	Pressurised Enclosures				
IEC 60079-7	Increased Safety			13	
IEC 60079-11	Intrinsic Safety			12	4
IEC 60079-15	Type of protection n			4	
IEC 60079-18	Encapsulation m			9	
IEC 60079-25	Intrinsicallysafety systems				
IEC 60079-29-1	Performance requirements of detectors for flammable gases				
IEC 60079-31	Equipment dust ignition protection by enclosure "t"			5	2

3.15 National accreditation

PRIMARA has DAkkS accreditation to ISO/IEC 17065 as a certification body. The certificate number is D-ZE-12089-01-00 is valid until February 2021 and a copy is shown at Annex B of this report. The link to the DAKKS site is

http://www.dakks.de/en/content/accredited-bodies-dakks?Regnr=D-ZE-12089-01-00

The scope of this accreditation include the national scheme for Ex Certificate which compliance to the ATEX Directive 2014/34/EU. The scope is available online on:

http://www.dakks.de/as/ast/d/D-ZE-12089-01-00.pdf

3.16 Assessment of manufacturers and issue of QARs

Procedure SOP-9-8 Section 3 addresses assessments of manufacturers. 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.

3.17 Comments (including issues found during assessment)

Issues were raised during the initial site assessment visit requiring action and a follow up visit by the assessment team. These were resolved and checked during the follow up assessment visit on 10+11 April 2017 with the corrective action reviewed and found compliant to allow the issues raised to be closed.

Minor issues were also found which were cleared to the satisfaction of the assessment team during the second site assessment visit.
These included:

- Management of competence
- Surveillance of manufacturer
- Complaints and appeals

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 Documents (TCD)

g) ExTAG decision sheets (DSs)

NOTE The latest editions of the above documents were applied.

4.2 ExTL persons interviewed

Name	Position
Harald Zelm	Project Review Engineer
Yilmaz Sezer	Project Review Engineer
Horst Haug	Project Review Engineer
Roland Kreitle	Project Engineer
Tanja Haupenthal	Project Engineer
Maximilian Pohl	Quality Manager
Maximilian Fischer	Project Engineer

4.3 Associated ExCB(s)

The ExTL is integral with the ExCB

4.4 Organisation

4.4.1 Names, titles and experience of the senior executives

Name	Title	Experience
Harald Zelm	Project Review Engineer	> 35 years

4.4.2 Name, title and experience of the quality management representative

Name	Title	Experience
Maximilian Pohl	Quality Manager	> 5 years

4.4.3 Other employees in ExTL activity

Name	Title/responsibility	Experience in Ex
Yilmaz Sezer	Project Review Engineer	> 10 years
Horst Haug	Project Review Engineer	> 20 years
Roland Kreitle	Project Engineer	> 1 years
Tanja Haupenthal	Project Engineer	> 2 years
Maximilian Fischer	Project Engineer	> 5 years

4.5 Organizational structure

See Annex A

4.6 Resources

The Ex operation at ZELM Ex has been successfully integrated into PRIMARA and has several professional and technical staff involved in Ex testing. It has a comprehensive range of testing equipment and good facilities for this type of testing.

4.7 Test reports issued

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

Standard numbers	Type of protection or other identifying information	Number of issued reports (ExTRs) (for last 4 years)			
		2014	2015	2016	2017
IEC 60079-0	General Requirements	2	3	28	5
IEC 60079-1	Flameproof enclosures			8	1
IEC 60079-2	Pressurised Enclosures				
IEC 60079-7	Increased Safety			13	
IEC 60079-11	Intrinsic Safety		1	12	4
IEC 60079-15	Type of protection n	2	2	4	
IEC 60079-18	Encapsulation m			9	
IEC 60079-25	Intrinsic safety systems				
IEC 60079-31	Protection by enclosure t				

4.8 National accreditation

While **ZELM Ex** has accreditation from DAkkS: Accreditation D-PL-19513-02-00 to ISO/IEC 17025:2005, which remains current. (A copy of the accreditation is attached at Annex C). The ZELM accreditation to ISO/IEC 17025 is being transferred to Primara and is expected during Q4 2017. Until this time, the current ZELM accreditation remains.

The link to the DAkkS site is:

http://www.dakks.de/en/content/accredited-bodies-dakks?Regnr=D-PL-19513-02-00

The online scope is available on

http://www.dakks.de/as/ast/d/D-PL-19513-02-00.pdf

The ISO/IEC 17025 accreditation scope of ZELM Ex includes EN 13463 series which are the previous and European version of ISO 80079-36 and -37.

This scope will be transferred to Primara, an application to DAkkS was sent already. The scope extension will be scheduled for Q4/2017.

4.9 Calibration

The majority of test equipment is sent out for calibration by an external calibration facility. These calibration facilities are DAkkS accredited.

However, the calibration procedure requires review to ensure that when test equipment is returned and has been adjusted or recorded as requiring adjustment. Action is taken in respect of reviewing previous results where the equipment has been used. See below

4.10 Proficiency

ZELM Ex/PRIMARA participates in the IECEx Proficiency testing organised by PTB. The results of the reference pressure tests and the temperature rise tests show that they are achieving good results. It has been confirmed that PRIMARA are continuing their involvement in the IECEx PTP

4.11 Comments (including issues found during assessment)

Twenty four issues requiring action were raised during the initial site assessment visit which required that the Assessment Team conducted a second visit. The second visit revealed that all items had been addressed to the satisfaction of the IECEx assessment team to enable it to recommend acceptance of the new Primara and their taking over of activities previously conducted by ZELM.

These included:

- Using of IECEx Operational Documents,
- Subcontracting of tests,
- Qualification of personnel,
- Review of ExTR,
- Technical issues regarding the Types of Protection

Minor issues were also found which were cleared to the satisfaction of the assessment team during the second site assessment visit.

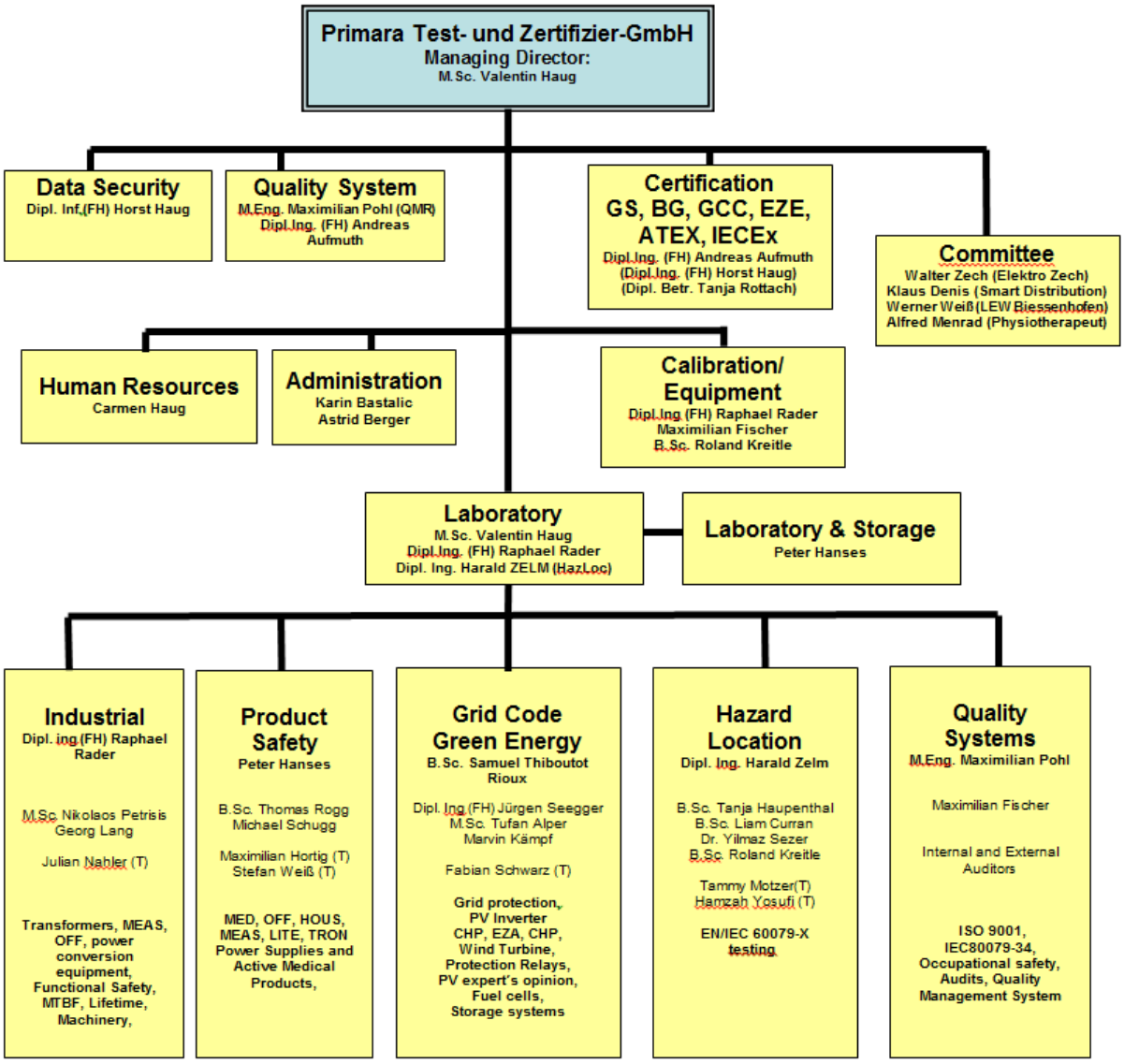
Annexes

ANNEX A Overall Organisation Chart

ANNEX B Accreditation Certificate for ISO/IEC 17065

ANNEX C Accreditation Certificate for ISO/IEC 17025 (relevant pages only)

Annex A
Overall Organisation Chart



Positions in brackets indicate the deputy responsibility of the staff.
Used Abbreviations within this document:
QMR: Quality Management Representative
T: Trainee

Annex B
Accreditation Certificate for ISO/IEC 17065

DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Beliehene gemäß § 8 Absatz 1 AkkStelleG i.V.m. § 1 Absatz 1 AkkStelleGBV
Unterzeichnerin der Multilateralen Abkommen
von EA, ILAC und IAF zur gegenseitigen Anerkennung

Akkreditierung

Die Deutsche Akkreditierungsstelle GmbH bestätigt hiermit, dass die Zertifizierungsstelle

Primara Test- und Zertifizier-GmbH
Gewerbestraße 28, 87600 Kaufbeuren

die Kompetenz nach DIN EN ISO/IEC 17065:2013 besitzt, Zertifizierungen von Produkten, Prozessen und Dienstleistungen in folgenden Bereichen durchzuführen:

-Geräte zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen i.S.d. Richtlinie 94/9/EG bis 19.04.2016 und 2014/34/EU ab 20.04.2016

- Sicherheit elektrischer und elektronischer Betriebsmittel
- Netzintegration von dezentralen Erzeugungseinheiten und Anlagen
- Umweltprüfverfahren

für die in der Anlage zu dieser Urkunde aufgeführten Verfahren und Produkte

Die Akkreditierungsurkunde gilt nur in Verbindung mit dem Bescheid vom 12.02.2016 mit der Akkreditierungsnummer D-ZE-12089-01 und ist gültig bis 11.02.2021.Sie besteht aus diesem Deckblatt, der Rückseite des Deckblatts und der folgenden Anlage mit insgesamt 03 Seiten.

Registrierungsnummer der Urkunde: **D-ZE-12089-01-00**

Frankfurt am Main, 12.02.2016

Im Auftrag Dipl.-Ing. (FH) Ralf Egner
Abteilungsleiter

Siehe Hinweise auf der Rückseite

Annex C
Accreditation Certificate for ISO/IEC 17025
(relevant pages only)

DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Beliehene gemäß § 8 Absatz 1 AkkStelleG i.V.m. § 1 Absatz 1 AkkStelleGBV
Unterzeichnerin der Multilateralen Abkommen
von EA, ILAC und IAF zur gegenseitigen Anerkennung

Akkreditierung

Die Deutsche Akkreditierungsstelle GmbH bestätigt hiermit, dass das Prüflaboratorium

Primara Test- und Zertifizier-GmbH
Gewerbestraße 28, 87600 Kaufbeuren

die Kompetenz nach DIN EN ISO/IEC 17025:2005 besitzt, Prüfungen in folgenden Bereichen durchzuführen:

Geräte zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen i.S.d. Richtlinie 2014/34/EU

Sicherheit elektrischer und elektronischer Betriebsmittel

Umweltsimulationsprüfungen

Netzintegration von dezentralen Erzeugungseinheiten

Die Akkreditierungsurkunde gilt nur in Verbindung mit dem Bescheid vom 27.03.2017 mit der Akkreditierungsnummer D-PL-12089-01 und ist gültig bis 28.02.2021. Sie besteht aus diesem Deckblatt, der Rückseite des Deckblatts und der folgenden Anlage mit insgesamt 32 Seiten.

Registrierungsnummer der Urkunde: **D-PL-12089-01-01**

Frankfurt am Main, 27.03.2017

Im Auftrag Dipl.-Ing. (FH) Ralf Egner
Abteilungsleiter

Siehe Hinweise auf der Rückseite

Deutsche Akkreditierungsstelle GmbH

Anlage zur Akkreditierungsurkunde D-PL-19513-02-00 nach DIN EN ISO/IEC 17025:2005

Gültigkeitsdauer: 28.03.2014 bis 27.03.2019 Ausstellungsdatum: 28.03.2014

Urkundeninhaber:

Prüf- und Zertifizierungsstelle Zelm Ex e.K.
Siekgraben 56, 38124 Braunschweig

Prüfungen in den Bereichen:

Geräte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen im Sinne der Richtlinie 94/9/EG

sowie

Sicherheits-, Kontroll- und Regelvorrichtungen für den Einsatz außerhalb von explosionsgefährdeten Bereichen im Sinne der Richtlinie 94/9/EG

Prüfungen nach:

- **Anhang III / EG Baumusterprüfung**
- **Anhang V / Prüfung der Produkte**
- **Anhang VI / Konformität mit der Bauart**
- **Anhang VII / Qualitätssicherung Produkt**
- **Anhang IX / Einzelprüfung**

verwendete Abkürzungen: siehe letzte Seite

1 Prüfung von Geräten und Komponenten zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen gemäß Richtlinie 94/9/EG

DIN EN 60079-0 2012-02	Explosionsgefährdete Bereiche - Teil 0: Betriebsmittel - Allgemeine Anforderungen *(zurückgezogene Norm)*

DIN EN 60079-0 2010-03	Explosionsfähige Atmosphäre - Teil 0: Geräte - Allgemeine Anforderungen *(zurückgezogene Norm)*
IEC 60079-0 2007	Explosive atmospheres - Part 0: Equipment - General requirements
DIN EN 60079-1 2008-04	Explosionsfähige Atmosphäre - Teil 1: Geräteschutz durch druckfeste Kapselung "d"
IEC 60079-1 2007	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"
DIN EN 60079-2 2008-07	Explosionsfähige Atmosphäre - Teil 2: Geräteschutz durch Überdruckkapselung "p"
IEC 60079-2 2007	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"
DIN EN 60079-5 2008-07	Explosionsfähige Atmosphäre - Teil 5: Geräteschutz durch Sandkapselung "q"
IEC 60079-5 2007	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"
DIN EN 60079-6 2008-02	Explosionsfähige Atmosphäre - Teil 6: Geräteschutz durch Ölkapselung "o"
IEC 60079-6 2007	Explosive atmospheres - Part 6: Equipment protection by oil immersion "o"
DIN EN 60079-7 2007-08	Explosionsfähige Atmosphäre - Teil 7: Geräteschutz durch erhöhte Sicherheit "e"
IEC 60079-7 2006	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"
DIN EN 60079-11 2007-08	Explosionsfähige Atmosphäre - Teil 11: Geräteschutz durch Eigensicherheit "i" *(zurückgezogene Norm)*
DIN EN 60079-11 2012-06	Explosionsgefährdete Bereiche - Teil 11: Geräteschutz durch Eigensicherheit "i"

IEC 60079-11 2011	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
DIN EN 60079-15 2011-02	Explosionsfähige Atmosphäre - Teil 15: Geräteschutz durch Zündschutzart "n"
IEC 60079-15 2010	Explosive atmospheres - Part 15: Equipment protection by type of protection "n"
DIN EN 60079-18 2010-07	Explosionsfähige Atmosphäre - Teil 18: Geräteschutz durch Vergusskapselung "m"
IEC 60079-18 2009	Explosive atmospheres - Part 18: Equipment protection by encapsulation "m"
DIN EN 60079-25 2011-06	Explosionsfähige Atmosphäre - Teil 25: Eigensichere Systeme
IEC 60079-25 2010	Explosive atmospheres - Part 25: Intrinsically safe electrical systems
DIN EN 60079-26 2007-10	Explosionsfähige Atmosphäre - Teil 26: Betriebsmittel mit Geräteschutzniveau (EPL) Ga
IEC 60079-26 2006	Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga
DIN EN 60079-27 2008-12	Explosionsfähige Atmosphäre - Teil 27: Konzept für eigensichere Feldbussysteme (FISCO) *(zurückgezogene Norm)*
IEC 60079-27 2008	Explosive atmospheres - Part 27: Fieldbus intrinsically safe concept (FISCO)
DIN EN 60079-28 2007-10	Explosionsfähige Atmosphäre - Teil 28: Schutz von Einrichtungen und Übertragungssystemen, die mit optischer Strahlung arbeiten
IEC 60079-28 2006	Explosive atmospheres - Part 28: Protection of equipment and transmission systems using optical radiation
DIN EN 60079-30-1 2007-12	Explosionsfähige Atmosphäre - Teil 30-1: Elektrische Widerstands-Begleitheizungen - Allgemeine Anforderungen und Prüfanforderungen

IEC 60079-30-1 2007	Explosive atmospheres - Part 30-1: Electrical resistance trace heating - General and testing requirements
DIN EN 60079-31 2010-07	Explosionsfähige Atmosphäre - Teil 31: Geräte-Staubexplosionsschutz durch Gehäuse "t"
IEC 60079-31 2008	Explosive atmospheres - Part 31: Equipment dust ignition protection by enclosure "t"
DIN EN 60079-35-1 2012-01	Kopfleuchten für die Verwendung in schlagwettergefährdeten Grubenbauen - Teil 35-1: Allgemeine Anforderungen - Konstruktion und Prüfung in Relation zum Explosionsrisiko
IEC 60079-35-1 2011	Explosive atmospheres Part 35-1: Caplights for use in mines susceptible to firedamp - General requirements - Construction and testing in relation to the risk of explosion
DIN EN 61241-4 2007-07	Elektrische Betriebsmittel zur Verwendung in Bereichen mit brennbarem Staub - Teil 4: Zündschutzart "pD"
IEC 61241-4 2001	Electrical apparatus for use in the presence of combustible dust - Part 4: Type of protection "pD"
DIN EN 61241-11 2007-07	Elektrische Betriebsmittel zur Verwendung in Bereichen mit brennbarem Staub - Teil 11: Schutz durch Eigensicherheit ""iD"" *(zurückgezogene Norm)*
IEC 61241-11 2005	Electrical apparatus for use in the presence of combustible dust - Part 11: Protection by intrinsic safety "iD"
DIN EN 62013-1 2007-02	Kopfleuchten für die Verwendung in schlagwettergefährdeten Grubenbauen - Teil 1: Allgemeine Anforderungen - Konstruktion und Prüfung in Relation zum Explosionsrisiko *(zurückgezogene Norm)*
IEC 62013-1 2005	Caplights for use in mines susceptible to firedamp - Part 1: General requirements - Construction and testing in relation to the risk of explosion
DIN EN 13463-1 2009-07	Nicht-elektrische Geräte für den Einsatz in explosionsgefährdeten Bereichen - Teil 1: Grundlagen und Anforderungen
DIN EN 13463-2 2005-02	Nicht-elektrische Geräte für den Einsatz in explosionsgefährdeten Bereichen - Teil 2: Schutz durch schwadenhemmende Kapselung 'fr'

DIN EN 13463-3 2005-07	Nicht-elektrische Geräte für den Einsatz in explosionsgefährdeten Bereichen - Teil 3: Schutz durch druckfeste Kapselung "d"
DIN EN 13463-5 2011-10	Nicht-elektrische Geräte für den Einsatz in explosionsgefährdeten Bereichen - Teil 5: Schutz durch konstruktive Sicherheit 'c'
DIN EN 13463-6 2005-07	Nicht-elektrische Geräte für den Einsatz in explosionsgefährdeten Bereichen - Teil 6: Schutz durch Zündquellenüberwachung "b"
DIN EN 13463-8 2004-01	Nicht-elektrische Geräte für den Einsatz in explosionsgefährdeten Bereichen - Teil 8: Schutz durch Flüssigkeitskapselung 'k';
DIN EN 1839 2004-01	Bestimmung der Explosionsgrenzen von Gasen und Dämpfen *(zurückgezogene Norm)*
DIN EN 12757-1 2006-01	Mischgeräte für Beschichtungsstoffe - Sicherheitsanforderungen - Teil 1: Mischgeräte zur Verwendung in der Fahrzeugreparaturlackierung *(zurückgezogene Norm)*
DIN EN 12757-1 Änderung 1 2010	Mischgeräte für Beschichtungsstoffe - Sicherheitsanforderungen - Teil 1: Mischgeräte zur Verwendung in der Fahrzeugreparaturlackierung
DIN EN 13821 2003-03	Explosionsfähige Atmosphären - Explosionsschutz - Bestimmung der Mindestzündenergie von Staub/Luft-Gemischen
DIN EN 14034-1 2004-12	Bestimmung der Explosionskenngrößen von Staub/Luft-Gemischen - Teil 1: Bestimmung des maximalen Explosionsdruckes pmax von Staub/Luft-Gemischen *(zurückgezogene Norm)*
DIN EN 14034-1 Änderung 1 2011	Bestimmung der Explosionskenngrößen von Staub/Luft-Gemischen - Teil 1: Bestimmung des maximalen Explosionsdruckes pmax von Staub/Luft-Gemischen
DIN EN 14034-2 2006-08	Bestimmung der Explosionskenngrößen von Staub/Luft-Gemischen - Teil 2: Bestimmung des maximalen zeitlichen Druckanstiegs (dp/dt)max von Staub/Luft-Gemischen *(zurückgezogene Norm)*

DIN EN 14034-2 Änderung1 2011	Bestimmung der Explosionskenngrößen von Staub/Luft-Gemischen - Teil 2: Bestimmung des maximalen zeitlichen Druckanstiegs (dp/dt)max von Staub/Luft-Gemischen
DIN EN 14034-3 2006-08	Bestimmung der Explosionskenngrößen von Staub/Luft-Gemischen - Teil 3: Bestimmung der unteren Explosionsgrenze UEG von Staub/Luft-Gemischen *(zurückgezogene Norm)*
DIN EN 14034-4 Änderung1 2011	Bestimmung der Explosionskenngrößen von Staub/Luft-Gemischen - Teil 4: Bestimmung der Sauerstoffgrenz-konzentration SGK von Staub/Luft-Gemischen
DIN EN 14522 2005-12	Bestimmung der Zündtemperatur von Gasen und Dämpfen
DIN EN 14591-1 2004-12 + Berichtigung1 2006-07	Explosionsschutz in untertägigen Bergwerken - Schutzsysteme - Teil 1: 2-bar-Wetterbauwerk
DIN EN 14591-2 2007-07	Explosionsschutz in untertägigen Bergwerken - Schutzsysteme - Teil 2: Passive Wassertrogsperren
DIN EN 14591-4 2007-09	Explosionsschutz in untertägigen Bergwerken - Schutzsysteme - Teil 4: Automatische Explosionslöschanlagen für Teilschnitt-maschinen
DIN EN 14973 2006-11	Fördergurte für die Verwendung unter Tage - Elektrische und brandtechnische Sicherheitsanforderungen *(zurückgezogene Norm)*
DIN EN 14973 Änderung1 2008	Fördergurte für die Verwendung unter Tage - Elektrische und brandtechnische Sicherheitsanforderungen
DIN EN 1498 2007-01	Explosionsschutz in untertägigen Bergwerken - Geräte und Schutzsysteme zur Absaugung von Grubengas
DIN EN 14986 2007-05	Konstruktion von Ventilatoren für den Einsatz in explosionsgefährdeten Bereichen
DIN EN 15794 2008-04	Bestimmung von Explosionspunkten brennbarer Flüssigkeiten *(zurückgezogene Norm)*

DIN EN 15967 2011-10	Verfahren zur Bestimmung des maximalen Explosionsdruckes und des maximalen zeitlichen Druckanstieges für Gase und Dämpfe
DIN EN ISO 16852 2010-09	Flammendurchschlagsicherungen - Leistungsanforderungen, Prüfverfahren und Einsatzgrenzen
DIN EN 50050 2007-04	Elektrische Betriebsmittel für explosionsgefährdete Bereiche - Elektrostatische Handsprüheinrichtungen

Mitgeltende Unterlagen

RL 94/9/EG 1994-03	Geräte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen
DIN EN 1127-1 2011-10	Explosionsfähige Atmosphären - Explosionsschutz - Teil 1: Grundlagen und Methodik
DIN EN 1127-2 2002-07	Explosionsfähige Atmosphären - Explosionsschutz - Teil 2: Grundlagen und Methodik in Bergwerken *(zurückgezogene Norm)*
DIN EN 1127-2 Änderung 1 2008	Explosionsfähige Atmosphären - Explosionsschutz - Teil 2: Grundlagen und Methodik in Bergwerken
DIN EN 1710 2006-01	Geräte und Komponenten für den Einsatz in explosionsgefährdeten Bereichen in unterirdischen Bergwerken *(zurückgezogene Norm)*
DIN EN 1710 Änderung 1 2008	Geräte und Komponenten für den Einsatz in explosionsgefährdeten Bereichen in unterirdischen Bergwerken
DIN EN 13160-1 2003-09	Leckanzeigesysteme - Teil 1: Allgemeine Grundsätze
DIN EN 13237 2003-11	Explosionsgefährdete Bereiche - Begriffe für Geräte und Schutzsysteme zur Verwendung in explosionsgefährdeten Bereichen *(zurückgezogene Norm)*

DIN EN 14491 2006-07 + Berichtigung1 2009	Schutzsysteme zur Druckentlastung von Staubexplosionen *(zurückgezogene Norm)*
DIN EN 14994 2007-05	Schutzsysteme zur Druckentlastung von Gasexplosionen
DIN EN 15198 2007-11	Methodik zur Risikobewertung für nicht-elektrische Geräte und Komponenten zur Verwendung in explosionsgefährdeten Bereichen
DIN EN 50104 2011-04	Elektrische Geräte für die Detektion und Messung von Sauerstoff - Anforderungen an das Betriebsverhalten und Prüfverfahren
DIN EN 50281-2-1 1999-11 + AC 1999	Elektrische Betriebsmittel zur Verwendung in Bereichen mit brennbarem Staub - Teil 2-1: Untersuchungsverfahren - Verfahren zur Bestimmung der Mindestzündtemperatur von Staub
DIN EN 15233 2007-11	Methodik zur Bewertung der funktionalen Sicherheit von Schutzsystemen für explosionsgefährdete Bereiche
EN 60079-20-1 2010-09	Explosionsfähige Atmosphären - Teil 20-1: Stoffliche Eigenschaften zur Klassifizierung von Gasen und Dämpfen - Prüfmethoden und Daten

2 Sicherheits-, Kontroll- und Regelvorrichtungen für den Einsatz außerhalb von explosionsgefährdeten Bereichen

EN 61241-0 2007-07	Elektrische Betriebsmittel zur Verwendung in Bereichen mit brennbarem Staub - Teil 0: Allgemeine Anforderungen *(zurückgezogene Norm)*
IEC 61241-0 2004	Electrical apparatus for use in the presence of combustible dust - Part 0: General requirements
EN 61241-1 2005-06	Elektrische Betriebsmittel zur Verwendung in Bereichen mit brennbarem Staub - Teil 1: Schutz durch Gehäuse "tD" *(zurückgezogene Norm)*
IEC 61241-1 2004	Electrical apparatus for use in the presence of combustible dust - Part 1: Protection by enclosures "tD"

EN 61241-18 2005-07	Elektrische Betriebsmittel zur Verwendung in Bereichen mit brennbarem Staub - Teil 18: Schutz durch Vergusskapselung "mD" *(zurückgezogene Norm)*
IEC 61241-18 2004	Electrical apparatus for use in the presence of combustible dust - Part 18: Protection by encapsulation "mD"
EN 62086-1 2006-05	Elektrische Betriebsmittel für gasexplosionsgefährdete Bereiche - Elektrische Widerstands-Begleitheizungen - Teil 1: Allgemeine Anforderungen und Prüfanforderungen *(zurückgezogene Norm)*
IEC 62086-1 2001	Electrical apparatus for explosive gas atmospheres - Electrical resistance trace heating - Part 1: General and testing requirements
DIN EN 1755 2000-06	Sicherheit von Flurförderzeugen - Einsatz in explosionsgefährdeten Bereichen - Verwendung in Bereichen mit brennbaren Gasen, Dämpfen, Nebeln oder Stäuben *(zurückgezogene Norm)*
DIN EN 1755 Änderung 2 2013	Sicherheit von Flurförderzeugen - Einsatz in explosionsgefährdeten Bereichen - Verwendung in Bereichen mit brennbaren Gasen, Dämpfen, Nebeln oder Stäuben

verwendete Abkürzungen:

DIN	Deutsches Institut für Normung e.V.
IEC	International Electrotechnical Commission
EN	Europäische Norm
RL	Richtlinie