eurofins | E&E	**IECEx QUALITY ASSESSMENT REPORT**	IEC IECEx Ex
Report No.:	**20CH-00698.X07**	**QAR No.: CH/SEV/QAR14.0001/04**

Project No.	**20CH-00698**			
Ex QMS Certificates	**QS SEV 18 ATEX 4165**			
Manufacturer Include Address with post code	Eugen Seitz AG Spitalstrasse 204 8623 Wetzikon Switzerland			
Production Site(s) audited Include Address with post code	Eugen Seitz AG Spitalstrasse 204 8623 Wetzikon Switzerland			
Product Description	Production and sale of ultrasonic components for separation, dry cleaning, dosing, cutting and conveying technologies			
Employee count	Total onsite: ~80	Total involved in Ex products: ~5		
Scope of Audit	Initial Assessment ☐	Surveillance Assessment ☒		
	Re-Assessment ☐	Special Assessment ☐		
Scheme	IECEx ☒	ATEX ☒		
Ex equipment with type(s) of protection	d ☒ e ☒ h ☐ i ☒ m ☒ n ☒ p ☐ t ☒ op ☐ Other *(specify)* ☐			
Audit Team Leader	Christian Ettlin			
Audit Date	2020-09-15			

Contents:

NOTE: whilst some parts of this form / template are optional there is an expectation that all ExCBs will

- use the form as published
- only add content, and
- not ignore the non-optional aspects

IECEx ExCB

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Eurofins Electric & Electronic Product Testing AG
ATEX Notified Body 1258
Luppmenstrasse 3, 8320 Fehraltorf,
SWITZERLAND

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1. Summary Report

Assessment Summary and Conclusions:

*(State the most important **results** and **conclusions** of the quality assessment)*

All requirements according to EN ISO/IEC 80079-34 and according to the new Directive 2014/34/EU annex IV fulfilled.
NO non-conformities listed.
All employees do have access to the internal information system to check the management system and processes. The quality claims are very high, all possible manufacturing steps are, as far as possible, automated.

Next Quality Audit due : 2021-09

Non-Conformities (refer to section 6)

(Indicate the Serial No.(s) of non-conformities recorded. Individual non-conformities are recorded on the non-conformity reports)

NCR No.(s): none

Audit Team Leader Recommendations

(Delete where not applicable)

☒ **Notification / Certification to be issued/maintained** once satisfactory technical assessment of the product is completed and a test report is issued

☐ **Notification / Certification to be issued/maintained*** following receipt of satisfactory documentary evidence supporting effective corrective action, and a test report is issued. Corrective action to be verified at next surveillance visit

☐ **Notification / Certification to be issued/maintained* following a satisfactory follow-up visit** and verification that corrective actions have been effectively documented and implemented, and test report issued.

☐ **Notification / Certification to be refused/suspended*** A further complete assessment to be conducted

☐ **Notification / Certification to be refused/suspended*** Close the application/withdraw the notification and inform the Scheme Administrator or other Notified Bodies.

Audit Team Leader Signature | **Technical Reviewer**

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2. Audit Information

2.1 Scope of Audit:

Type A initial assessment/reassessment of manufacturer **with** a certified QMS* ☐

Type B initial assessment/reassessment of manufacturer **without** a certified QMS ☐

Type C surveillance of manufacturer **with** a certified QMS* ☒

Type D surveillance of manufacturer **without** a certified QMS ☐

** where manufacturer has a certified quality system, include certification/registration body, date of registration, certificate No. and scope or append a copy of the certificate (including scope)*

2.2 Audit Criteria

List any other reference documents, against which Audit was conducted

:

ISO/IEC 80079-34, Ed. 2.0:2018 ☒

Other applicable reference Standards ☐

Other applicable reference Standards ☐

Other applicable reference Standards ☐

2.3 Date(s) and Duration of Audit

Include total number of auditor days on site

: 2020-08-21, 1 day assessment

2.4 Certified Quality System

ISO 9001 Certificate No	Certified by	Expiry date	Scope
10-304-111	Swiss Safety Center	2022-02-23	Entwicklung, Herstellung und Vertrieb von Produkten anspruchsvoller Ventiltechnologie

If ISO 9001 certified, were non-conformities from the last ISO 9001 audit reviewed?

Yes ☐ No ☒ N/A (no NCs) ☐

Comments to ISO 9001 non-conformities.

none

2.5 Composition of Audit Team:

Name	Position	Role in Audit *(Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)*
Christian Ettlin	QAR Auditor	Sole Auditor
Patrick Gutensohn	Product Certification	Technical Reviewer

2.6 Interviewed Representatives of Manufacturer (Auditee):

Name	Position
Mr. Rupert Bier	Ex-responsible person at Seitz AG
Mr. Michael Paschka	Head of Quality Management
Mr. Roland Fischer	Head of TD

2.7 External Providers: (*Use this table to list External Providers reviewed during audit of supplier evaluation)*

Name of Supplier	Critical item or service provided
Magnet-Schulz	Solenoids, EN ISO/IEC 80079-34
Nass Magnet	Solenoids, EN ISO 80079-34
KUK Electronic AG	Electronic Assembly EN ISO 9001:2015

2.8 Manufacturers Documentation:

(*Use this table to list details of the manufacturers quality management system documentation cited in Section 3 by document identity and reviewed during the audit covered by this Quality Audit Report)*

Document No.	Document Name	Rev.	Date
10-304-111	Eugen Seitz AG ISO 9001:2015/ ISO 14001:2015 Certificate issued by Swiss Safety Center ICG, valid until 2022-02-23	---	2019-02-21
---	Organigramm Zentrale Technik	---	2019-01-01
---	Stellenbeschreibung Ex-Schutz Beauftragter	---	2017-06-20
---	Verkaufsprozess	03	2011-0216
---	Ex-Grundschulung	---	2020-10
001242564	Produkrückruf Prozess	00	2017-03-08
---	Gap Analyse 14F52 EN 60079-0:2009 to EN 60079-0:2012+A11:2013	---	---
---	Gap Analyse 14x80 EN 60079-0:2009 to EN 60079-0:2012+A11:2013	---	---

2.9 Audit report history

Revision	Description	Free Reference Number	Issue date
---	Initial Assessment ATEX Electrosuisse	10-IK-0487.01	2011-01-31
---	Surveillance Assessment ATEX Electosuisse	10-IK-0487.02	2012-01-17
00	Re-Assessment IECEx Electrosuisse	10-IK-0487.03	2014-01-16
01	Surveillance Assessment Electosuisse	10-IK-0487.04	2015-07-09
02	Re-Assessment Electrosuisse	10-IK-0487.05	2017-02-13
03	Initial Assessment Eurofins Electrosuisse	18-Ex-0133.01	2018-09-05
04	Surveillance Assessment Eurofins E&E postponed because of Sars Covid-19	20CH-00698.X07	2020-09-15

3. Documentation Review and Assessment of Implementation

Note 1: Regarding the entry of Manufacturer's Document References in the following table - you only need to reference the document number (and if desired the title) if the details of document number, title and revision status are listed in Clause 2.8. Comments are to be entered by the auditor to document compliance or noncompliance of a clause.

Note 2: Even when there are no additional IEC/ISO 80079-34:2018 requirements to ISO 9001:2015 the auditor shall provide a verdict in accordance with the Note 3 below.

Note 3: Possible audit verdicts: P = Pass, NA = Not applicable, F = Fail, add the Non-conformity number against a clause where a Non-conformity has been issued.

Clause	Requirement	Documents or Comments	Verdict
4.1	**Understanding the organization and its context** 4.1 of ISO 9001:2015 applies with the following addition:		
In regard to this document, the context of the organization is to ensure that any Ex Product is in accordance with its certificate and technical documentation.		The quality assurance systems ensure conformity of Ex-products as defined in certificate and tech. documentation.	**P**
4.2	**Understanding the needs and expectations of interested parties** 4.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
4.3	**Determining the scope of the quality management system** 4.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
4.4	**Quality management system and its processes** 4.4 of ISO 9001:2015 applies with the following addition:		
The quality management system shall ensure that the Ex Product conforms to the type described in the certificate and the technical documentation.		The quality assurance systems ensure conformity of Ex-products as defined in certificate and tech. documentation.	**P**
5.1.1	**General** 5.1.1 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
5.1.2	**Customer focus** 5.1.2 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
5.2.1	**Establishing the quality policy** 5.2.1 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
5.2.2	**Communicating the quality policy** 5.2.2 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
5.3	**Organizational roles, responsibilities and authorities** 5.3 of ISO 9001:2015 applies with the following additions:		
Ex authorized person(s) shall be appointed with defined and documented responsibilities and authority to ensure the following requirements are met:			
a) the effective co-ordination of activities with respect to Ex Products;		Ex-responsible person is Ruppert Bier. Responsibilities and authority defined. Product changes have to be coordinated if required with certification body.	**P**
b) the liaison with the issuer of the certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the certificate and the technical documentation;		Product changes have to be coordinated if required with certification body.	**P**
c) the liaison with the body responsible for the verification of the quality management system with respect to intended updating of the quality management system; NOTE: It is not practicable for the manufacturer to inform the body responsible for the verification of the quality management system each time the quality management system is updated. It is only practicable to inform		Changes of the quality system are reported to the certification body.	**P**

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them of "substantial" updating of the quality management system relevant to the Type of Protection. Similarly, it is not practicable to specify in general terms what types of updating are or are not "substantial". It is therefore normal that the manufacturer informs the body responsible for the verification of the quality management system on any update of the quality management system having consequences on Ex Product compliance. The change of an Ex authorized person is considered as a "substantial" change.			
d) the authorization of initial approval and changes to related drawings, where appropriate;		Product changes have to be coordinated if required with certification body.	**P**
e) the authorization of concessions (see 8.7 f));		Concessions need authorization of Ex-responsible person Rupert Bier.	**P**
f) the accuracy of relevant information regarding Ex Product given to the customer for any sales literature and installation instructions (which shall include applicable Specific Conditions of Use and any Schedule of Limitations); NOTE: Ex Equipment Certificate numbers with a suffix "X" contain Specific Conditions of Use. Ex Component certificates numbers, with a suffix "U" may contain a Schedule of Limitations.		Ex relevant information is checked by the Ex-responsible person and Engineering.	**P**
g) the effective coordination of manufacturing processes related to Ex Products including externally provided products, services and processes detailed in 8.4; In the case of a manufacturer with multiple manufacturing sites an Ex authorized person with relevant responsibilities shall be appointed for each site.		The Ex-responsible person is involved into the manufacturing process. On manufacturing in Wetzikon site.	**P**
Records demonstrating this shall be available and be maintained as documented information.		All records in the PDM system as requested by this standard are available and retained for at least 10 years.	**P**
6.1	**Actions to address risks and opportunities** 6.1 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
6.2	**Quality objectives and planning to achieve them** 6.2 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate). Document "Qualitäts- und Umweltziele und Massnahmen 2020. *Document reviewed while Audit*	**P**
6.3	**Planning of changes** 6.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
7.1.1	**General (Support and Resources)** 7.1.1 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
7.1.2	**People** 7.1.2 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
7.1.3	**Infrastructure** 7.1.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
7.1.4	**Environment for the operation of processes** 7.1.4 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
7.1.5	**Monitoring and measuring resources** 7.1.5 of ISO 9001:2015 applies with the following addition:		
When monitoring or measuring is used to verify the conformity of Ex Products, the measuring equipment shall be calibrated and a valid calibration certificate shall exist. Verification of measuring equipment against calibrated equipment is also permitted as long as it is properly documented.		Each measuring equipment has its own number and is traced by a ERP system software tool Babtec. The equipment's are calibrated internal and external	**P**

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The calibration certificate shall meet one of the following requirements:		from accredited Calibration Labs.	
a) Where a calibration certificate bears an accreditation, logo issued by an accredited calibration laboratory (which can demonstrate that it operates in compliance with an internationally recognized standard and is covered by a multilateral international agreement) the calibration laboratory need not be subjected to further evaluation.		Relevant instruments regularly (2 years) calibrated by accredited Cal-Labs Testo and Wenzel Certificate bears all required information an accreditation logo.	**P**
b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information: • an unambiguous identification of the item calibrated; • evidence that the measurements are traceable to international or national measurement standards; • the method of calibration; • a statement of compliance with any relevant specification; • the calibration results; • the uncertainty of measurement, where necessary; • the environmental conditions, where relevant; • the date of calibration; • the signature of the person under whose authority the certificate was issued; • the name and address of the issuing organization and the date of issue of the certificate; • a unique identification of the calibration certificate.		Only certificates with logo.	**N/A**
c) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority or does not contain the information listed in 7.1.5 b), the manufacturer shall demonstrate a valid relationship to international or national measurement standards by other means (e.g. a documented site assessment).		Only certificates with logo.	**N/A**
7.1.6	**Organizational knowledge** 7.1.6 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate). Support from Eurofins if necessary.	**P**
7.2	**Competence** 7.2 of ISO 9001:2015 applies with the following addition:		
The manufacturer shall have a documented process to identify and ensure that all persons having an impact on the compliance of Ex Products are trained and competent. NOTE 1: Parties who might have an impact on the compliance of Ex Products are the Ex authorized person(s), manufacturing, inspecting, testing, sales, marketing, supply management, calibration and quality control services and other services. NOTE 2: Competence requirements of 7.2 also address the awareness of 7.3.		The Ex-responsible person takes part in explosion protection training courses egg. Thuba, PTB and self-training. therefore he is competent. Training and competence matrix, training records for each employee available.	**P**
7.3	**Awareness** 7.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
7.4	**Communication** 7.4 of ISO 9001:2015 applies with the following addition:		
Internal and external communication relating to Ex Products **shall be controlled.** NOTE 1: Communication includes manufacturer documentation, technical documentation, certificates, nonconforming products placed on the market, etc. NOTE 2: External communication includes communication with clients, certification bodies, providers, economic operators (authorized representatives, importers, distributors, external providers...), authorities etc.		Ex relevant information is checked by the Ex authorized person. ERP process regarding claims in place and used if necessary. Non-compliant parts will be destroyed or used for analysis Responsibilities defined and documented. (org charts)	**P**

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		major technical changes have to be discussed with CB.	
7.5.1	**(Documented information) General** 7.5.1 of ISO 9001:2015 applies with the following addition:		
All requirements and provisions adopted by the manufacturer to ensure compliance of Ex Products with their certificates and technical documentation, and to demonstrate compliance to this document, shall be appropriately documented in a systematic and orderly manner. This may be achieved in the form of manuals, policies, procedures, instructions, flowcharts, spread sheets, forms, or other appropriate means. The quality management system documentation shall permit a consistent interpretation of quality programs, plans, manuals and records		Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate). Quality Manual is computer based and was reviewed during Audit.	**P**
7.5.2	**Creating and updating** 7.5.2 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
7.5.3	**Control of documented Information** 7.5.3 of ISO 9001:2015 applies with the following addition:		
a) technical documentation and manufacturer's documentation shall be controlled;		Detailed documentation and manufacturing procedures including documentation maintenance in ERP and QM-system POMS "process oriented management system" Storage of documents > 10 years.	**P**
b) documented procedures shall ensure that information contained within manufacturer's documentation is compatible with the technical documentation. The manufacturer shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings;		The stored drawings on the system are the valid ones. Changes have to be approved by Ex authorized person.	**P**
c) the quality management system shall ensure that no factor (type, characteristic, position etc.) defined within the certificate and technical documentation (e.g. schedule drawings) is modified unless otherwise permitted by the issuer of the certificate;		Changes have to be approved by Ex authorized person. The quality management system ensures compliant Ex-products.	**P**
d) there shall be a documented system that refers all related drawings to the relevant schedule drawings;		Drawings for Ex-components are accordingly marked.	**P**
e) where there are common schedule drawings associated with more than one certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings; NOTE: Some manufacturers use common components with common drawing numbers on more than one product and then have more than one person responsible for the end products. A compliant QMS would assure that the change to the component for the one product is not implemented without approval from the responsible persons for all end-products that use that component.		No such drawings.	**N/A**
f) where a manufacturer also has drawings for products that are not Ex Products, the manufacturer shall have a system that enables both the related drawings and schedule drawings to be clearly identified; NOTE: The following examples indicate some methods to achieve this: – the use of visual markers; – the use of a unique series of drawing numbers, e.g. all drawings concerning a certified Ex Product have an Ex prefix to the drawing number; – the use of a computerized relational database with indentured "Bills of Materials" that identify all Ex critical documents, components and controls unauthorized changes can also be acceptable.		Drawings for Ex-components are accordingly marked. Ex products are not used for non-ex.	**P**
g) the manufacturer shall document the body responsible for the verification of the quality management system of each certificate;		Different bodies responsible, documented.	**P**

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NOTE: In some Certification Schemes, the body responsible for the verification of the quality management system associated with each certificate can be different from the body that issued the certificate.			
h) where technical documentation or manufacturer's documentation are passed to a third party, they shall be provided in a way that is not misleading;		Regarded.	**P**
i) the manufacturer shall have a documented process to annually check the validity of all Ex related certificates, standards, regulations and other external specifications;		Recorded in the processes, in responsibility of Ruppert Bier	**P**
j) the manufacturer shall retain adequate quality records to demonstrate conformity of the Ex Products. A minimum of 10 years retention after each Ex Product (batch) has been placed on the market is required. As a minimum, the list of quality records requiring control and retention, as far as applicable, shall be: • those arising from regulatory requirements; • quality documented information • responsibilities and authorities for Ex relevant roles assignment and communication within the organization • customer order; • contract review; • training records; • design and development changes; • inspection and test data (per batch); • calibration data; • manufacturing traceability; • sub-contractor evaluation; • delivery data (customer, delivery date and quantity, including serial numbers where available); • other documented information, if needed.		All records as requested by this standard are available and retained for at least 10 years.	**P**
8.1	**Operational planning and control** 8.1 of ISO 9001:2015 applies with the following addition:		
The information in Annexes A and B for control and acceptance of processes for Ex Products are one method to ensure compliance with the requirements of the certificate. If other methods are used, they should be evaluated to ensure full compliance with the requirements of certification.		Annexe A is used.	**P**
8.2.1	**Customer Communications** 8.2.1 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
8.2.2	**Determining the requirements for products and services** 8.2.2 of ISO 9001:2015 applies.	nfirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
8.2.3	**Review of the requirements for products and services** 8.2.3 of ISO 9001:2015 applies with the following addition:		
The review shall ensure that any stated customer requirement is compatible with the certificate e.g. equipment group, temperature class, Type of Protection, Equipment Protection Level (EPL) and ambient temperature range. In some situations, such as internet sales, a formal review might be impractical. In such a case the appropriate information shall be made available to the customer.		Orders are checked according to the ex-relevant parameters and requirements. Only standard Ex-products are sold, no customer requirements are taken into account. Information for standard products are publish on Internet or passed on customer meetings.	**P**
8.2.4	**Changes to requirements for products and services** 8.2.4 of ISO 9001:2015 applies with the following addition:		
The Ex authorized person(s) identified in 5.3 shall be involved in any changes (e.g. changes to the manufacturer's documentation,		Ex relevant information is checked by the Ex authorized person.	**P**

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quality management system or marketing documents) that could affect Ex Product compliance.			
8.3.1	**General (Design and development of products and services)**		**N/A**
	8.3.1 of ISO 9001:2015 is not within the scope of this document.		
8.3.2	**Design and development planning**		
	8.3.2 of ISO 9001:2015 is not within the scope of this document.		
8.3.3	**Design and development Inputs**		
	8.3.3 of ISO 9001:2015 is not within the scope of this document.		
8.3.4	**Design and development controls**		
	8.3.4 of ISO 9001: 2015 is not within the scope of this document.		
8.3.5	**Design and development outputs**		
	8.3.5 of ISO 9001:2015 is not within the scope of this document.		
8.3.6	**Design and development changes** 8.3.6 of ISO 9001:2015 applies with the following addition:		
The Ex authorized person(s) identified in 5.3 shall be involved in the approval process of any substantial modification or change (e.g. changes to the manufacturer's documentation, quality management system or marketing documents) that could affect Ex Product compliance.		Any design changes have to be approved by Ex authorized person or if required also by involved certification body.	**P**
8.4.1	**General (Control of externally provided processes, products and services)** 8.4.1 of ISO 9001:2015 applies with the following addition:		
a) while manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the certificate and the technical documentation shall not be sub-contracted;		Regarded, responsibility is subcontracted for Ex "d" enclosures of solenoid valves.	**P**
b) external providers providing a product, process, or service that can affect the Ex Product's compliance with the certificate shall only be selected after an evaluation has provided evidence that they have the capability of ensuring compliance with all specified requirements; 1) documented objective evidence that the external provider can provide product, process or service that is fit for purpose shall be made by one or more of the following methods: – the external provider has an acceptable Ex quality management system according to this document assessed by an accredited body, – the external provider has a quality management system certificate in accordance with the appropriate standard and with an acceptable scope, NOTE A certificate issued by an accredited body which can demonstrate that it operates in compliance with ISO/IEC 17021 is generally acceptable; depending on the nature of the product, process, or service, a quality management system in accordance with ISO 9001:2015 might not be sufficient. – a documented site assessment to ensure that all relevant controls are available, documented, understood and effective. NOTE: The evaluation takes the following into account: – criticality of the product, process or service; – degree of difficulty, or variability in the manufacturing process; – location of the external provider and hence the effectiveness of communications; – subcontracting of the product, process or service.		Process clear defined with instructions in all relevant documents. Suppliers will be regularly (re)evaluated and have to guarantee requested characteristics and quality.	**P**
2) where the features affecting the Type of Protection cannot be verified at a later stage or are not verified by the manufacturer e.g. encapsulated intrinsically safe circuits, then the product, process, or service shall only be accepted by one of the following methods: – the manufacturer can demonstrate that the control process implemented by the external providers ensures Ex compliance,		Supplier deliver a conformity statement for the dimensions. Supplier is ISO 9001 certified. Supplier for solenoids has a Quality system EN ISO/IEC 80079-34. Incoming inspection acc. to conformity declarations or/and visual inspections, where	**P**

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	– the body responsible for the verification of the quality management system performs periodic audits at the external providers.	required measurements and tests.	
	c) external providers providing calibration services (including verification on measuring devices by comparison with calibrated equipment) shall be evaluated on their ability to meet stated requirements as well as the requirements of 7.1.5;	Regarded, refer to clause 7.1.5.	**P**
	d) external providers not used for a period exceeding one year shall be re-evaluated in accordance with 8.4.1 b) prior to the placing of a contract or a purchase order;	Regularly contact with suppliers.	**P**
	e) requirements 8.4.1 b) and 8.4.1 d) are not mandatory for products, processes or services where the manufacturer verifies conformance according to 8.4.2;	Regarded, refer to clause 8.4.2.	**P**
	f) the ongoing ability of the external providers to provide conforming product, process or service shall be reviewed at periods not exceeding one year; NOTE 1: "Review" is a process by which the manufacturer demonstrates the ongoing suitability and performance in accordance with 8.4.1 b) and c) of their external providers e.g. receiving inspection report analysis. NOTE 2: The terms "re-evaluation" and "review" have different meanings.	Regularly contact with suppliers. Suppliers are ISO 9001 certified or has a Quality system EN ISO/IEC 80079-34.	**P**
	g) The manufacturer shall facilitate an arrangement whereby the body responsible for the verification of the Ex quality management system may also verify aspects of any external provider's operation that affects the Type of Protection.	Regarded, body can also audit external suppliers.	**P**
8.4.2	**Type and extent of control** 8.4.2 of ISO 9001:2015 applies with the following addition:		
	a) for purchased processes, products and services that can compromise the Type of Protection, the manufacturer shall determine and implement verification arrangements which demonstrate the product's compliance with the certificate, considering the nature of the product and the nature of the external provider;	Incoming verification for Ex-relevant components as required.	**P**
	b) when deciding what type of verification is required for a particular purchased process, product or service, the manufacturer shall consider the nature of the purchased product, the external provider, and how critical it is to the Type of Protection. In considering whether the external provider should carry out the verification, the manufacturer should consider the results of their evaluation carried out under 8.4.1. The decision should reflect the competence of the external provider, including whether they have a quality management system that covers the activity, the resources, e.g. equipment, and the people with sufficient skill and experience to do it. This latter point is particularly significant when judgement is required, such as when inspecting a flameproof casting. When the manufacturer elects to have the external provider carry out test or inspection that is relevant to the Type of protection, the product may be supplied with a declaration of conformity that confirms it has been done;	Regarded, process in place.	**P**
	c) where the external provider has been evaluated and documented objective evidence has been obtained to demonstrate that the external provider is fully capable of producing and verifying the process, product or service, no further verification of the process, product or service is required, if a declaration of conformity is supplied for each batch or product;	Regarded, process in place.	**P**
	d) where the certificate specifies routine tests or inspections, these shall be carried out on each and every product. They may be carried out by either the external provider or the manufacturer. When carried out by the external provider they shall be specified on the purchasing documents, e.g. by a quality plan, and confirmed by	Regarded, process in place.	**P**

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	the external provider e.g. by a declaration of conformity including test results, if required;		
	e) where verification of a purchased product cannot be carried out after manufacture, e.g. the internal parts of an encapsulated intrinsically safe circuit, then the product shall only be accepted if supplied with a declaration of conformity. This shall specifically state compliance to the purchase documents, e.g. a quality plan, that lists the factors that together demonstrate conformity of the product;	Not used for the product.	**N/A**
	f) where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch;	Regarded, process in place.	**P**
	g) where either the external provider or the manufacturer requires training or specialist skill or knowledge to carry out a verification, then the training material, specialist skill, knowledge or background shall be documented, and training records maintained;	Regarded, process in place.	**P**
	h) where the manufacturer chooses not to carry out inspections and tests at its own premises, then inspections and tests shall be performed on the external provider's premises under the responsibility of the manufacturer;	100 % in house end tests where not delegated to subcontractor.	**P**
	i) where an external provider provides product with evidence of conformity applicable to use in an explosive atmosphere, (e.g. certificate), then further verification is not required unless the manufacturer considers it necessary;	Refer 8.4.1. 2). Random sample tests can be made.	**P**
	j) Where a verification of purchased product is relative to material (metals, alloys, nonmetallic parts, resins and similar), a specific analysis certificate or declaration shall be supplied;	Regarded, process in place.	**P**
	k) One of the following processes shall be used to verify the continued conformity of the materials critical to the applied Type of Protection, used in the production of the Ex Products: 1) Review the Declaration(s) of Conformity from the external provider of the material within the supply chain that can impact the material characteristics; as applicable; to demonstrate that the material used in the production of the Ex product is in accordance with the schedule drawings. 2) Review the material manufacturer's confirmation that the material maintains the particular material properties of concern; e.g. flammability, CTI, RTI, or UV resistance, chemical composition, physical properties. 3) Review the material manufacturer's process and data for the validation of material characteristics. 4) Confirmation that equipment testing, necessary to confirm the material is in accordance with the certificate or schedule drawings, is repeated as required Alternative processes may be utilized if it can be demonstrated that they provide the same level of conformity. Receipt or acceptance of a declaration of conformity does not absolve the manufacturer from responsibility to ensure continuing conformity. NOTE: Annex C provides guidance for the development of an external provider's declaration of conformity.	Regarded, process in place.	**P**
8.4.3	**Information for external providers** 8.4.3 of ISO 9001:2015 applies with the following addition:		
	a) the purchasing documents shall clearly describe the specific requirements pertaining to externally provided product set out in the certificate and the technical documentations (e.g. for process control, testing or inspection); NOTE: For particular types of product e.g. castings, machined items and assemblies, the purchasing documents commonly include specific references to required drawings, test procedures, inspection procedures, material certificates, test reports and Declarations of Conformity.	Purchase information includes Ex- statements where applicable.	**P**

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	b) for items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item;	Refer 8.4.1. 2).	**P**
	c) the manufacturer shall define the method by which documents e.g. technical specifications, stated in a particular purchase order remain traceable to the order;	Regarded, process in place.	**P**
	d) where the manufacturer does not provide such documents with subsequent orders, then the manufacturer shall have documented procedures for ensuring that external providers have current copies of documents and that their integrity be maintained.	The external provider always receives the necessary documents	**P**
8.5.1	**Production and service provision (Control of production and service provision)** 8.5.1 of ISO 9001:2015 applies with the following addition:		
	The manufacturer shall provide procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the Ex Product with its technical documentation.	Fulfils the requirements Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
	Where a process can affect the integrity of a Type of Protection, and where the resulting integrity cannot be verified after manufacture (e.g. the environmental conditions required for curing an encapsulant), that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters (Annex A can be used to demonstrate compliance).	Fulfils the requirements Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
8.5.2	**Identification and traceability** 8.5.2 of ISO 9001:2015 applies with the following addition:		
	a) the manufacturer shall establish and maintain procedures for product identification during all stages of production, testing, final inspection and placing on the market;	Ex-products are specially marked. Traceability and identification assured back to Production date: week/year, possible.	**P**
	b) traceability is required with respect to the final product and its significant parts. Traceability can be achieved using serial number, batch or other acceptable method. NOTE: Significant parts are, for example, a printed circuit board (PCB) and safety component of an intrinsically safe circuit, but not each electronic component on a PCB. The significant part can be defined in the technical documentation during the processes of the product assessment.	Ex-products are specially marked. Traceability and identification assured back to Production date: week/year, possible.	**P**
8.5.3	**Property belonging to customers or external providers** 8.5.3 of ISO 9001:2015 applies with the following addition:		
	It is the responsibility of the manufacturer to verify the compatibility of a product supplied by a customer or an external provider with the requirements of the certificate.	Random sample tests can be made.	**P**
8.5.4	**Preservation** 8.5.4 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
8.5.5	**Post-delivery activities** 8.5.5 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
8.5.6	**Control of changes** 8.5.6 of ISO 9001:2015 applies with the following addition:		
	The Ex authorized person(s) identified in 5.3 shall be involved in changes (e.g. changes to the manufacturer's documentation, quality management system or marketing documents) that could affect Ex Product compliance.	Any design changes have to be approved by Ex authorized person or if required also by involved certification body.	**P**
8.6	**Release of products and services** 8.6 of ISO 9001:2015 applies with the following addition:		
	Where routine tests are required by the certificate and technical documentation, these tests shall be performed as specified. Unless specifically permitted by the certificate and the technical documentation, statistical methods shall not be used.	Working environment as well as instructions and test benches ensure compliant production. All	**P**

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		relevant processes validated and documented.	
Ex Products shall only be released after final inspection and testing have been satisfactorily completed. The manufacturer shall provide customers with instructions prepared in accordance with the relevant standards or statutory and regulatory requirements, including any Specific Conditions of Use or particulars of possible misuse.		100 % in house end tests.	**P**
8.7	**Control of nonconforming outputs** 8.7 of ISO 9001:2015 applies and the following shall be defined:		
a) the manufacturer shall maintain a documented system, such that in the event of an Ex Product not conforming to the certificate and having been supplied, then the manufacturer's customer can be identified;		Each product can be traced at least to Eugen Seitz AG end user or dealer. Recall actions are easily possible by internal documentation.	**P**
b) the manufacturer shall take action appropriate to the degree of risk, where nonconforming Ex Product has been supplied to a customer. It is recommended that the manufacturer liaise with the body responsible for the issue of the certificate;		Regarded, process in place.	**P**
c) where unsafe nonconforming Ex Products have been supplied to a customer, the manufacturer shall, in writing, inform its customer and the body responsible for the verification of the quality management system and the issuer of the certificate;		Regarded, process in place.	**P**
d) where it is not possible to trace unsafe nonconforming Ex Products (e.g. Ex Products supplied via a distributor, or for high volume Ex Products such as Cable Glands) then a notice shall be placed in appropriate publications providing recommended action to be taken;		Regarded, process in place.	**P**
e) for all nonconforming Ex Products that have been supplied to a customer, the manufacturer shall maintain, for a minimum period of 10 years, records of: 1) serial numbers or identification of Ex Products supplied; 2) the customer who received the Ex Products; 3) the action taken to inform customers and the body responsible for the verification of the quality management system in the case of unsafe nonconforming Ex Products; 4) the action taken to implement corrective and preventative action;		Regarded, process in place.	**P**
f) concessions for Ex Products that take the Ex Products outside the design as defined in the certificate and technical documentation are not permitted.		Regarded, process in place.	**P**
9.1.1	**General (Monitoring, measurement, analysis and evaluation)** 9.1.1 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
9.1.2	**Customer satisfaction** 9.1.2 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
9.1.3	**Analysis and evaluation** 9.1.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
9.2	**Internal audit** 9.2 of ISO 9001:2015 applies with the following addition:		
a) The audit program shall address the effectiveness of the elements of the quality management system as described in this document to ensure that the Ex products are in conformity with the certificate. The maximum period between audits shall not exceed 14 months.		According internal audit plan, each division audited at least once in 3 years. Partially internal audits are carried out annually. Ex-Aspects assessed every year.	**P**

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	b) One method of demonstrating effectiveness is the use of vertical auditing whereby an Ex Product awaiting dispatch is used to prove the system. The auditor examines all aspects of the system associated with the production of that Ex Product from a certification viewpoint. This normally includes appropriate documentation (drawings, inspection checklists, test records, material certificates etc.), Ex Product identification, handling, storage, training of staff and any other elements of the system which can affect the compliance of the Ex Product to the certification parameters.	Not conducted.	**N/A**
	c) For those manufacturers that employ checklists to assist in their internal audit programs, the inclusion of the requirements of this document into the appropriate checklists, and the retention of internal audit records, is an alternative method of addressing this requirement. Manufacturers may employ either method or some other equivalent method.	Regarded, process in place.	**P**
9.3.1	**Management review (General)** 9.3.1 of ISO 9001:2015 applies with the following addition:		
	a) the maximum intervals between reviews shall not exceed 14 months; b)top management shall chair the review; c)the Ex authorized person(s) responsible for the activities as detailed in 5.3 shall participate in the review. The review shall include the overall effectiveness of the quality management system with respect to Ex Products, including results of internal and external audits. NOTE: Review of results of internal and external audits would provide evidence of the effectiveness of the quality management system.	Regular reviews once a year executed and chaired by top management. Assessments do include Ex-relevant issues. Ex authorized person is generating a report.	**P**
9.3.2	**Management review inputs** 9.3.2 of ISO 9001: 2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
9.3.3	**Management review outputs** 9.3.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
10.1	**General (Improvement)** 10.1 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
10.2	**Nonconformity and corrective action** 10.2 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**
10.3	**Continual improvement** 10.3 of ISO 9001:2015 applies.	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	**P**

Annex A (informative)	
Information relevant to particular Types of Protection and specific Ex Products	
A.1	**Overview**
This annex provides information on those aspects that the quality management system should address with respect to particular types of protection. It does not add to or otherwise change the requirements of this document. This annex provides examples of how to meet the requirements of this document, recognizing that other methods which achieve the same objectives are equally acceptable; and draws attention to aspects of requirements that might not be readily apparent to those unfamiliar with quality management systems for products intended for use in explosive atmospheres. NOTE: The following examples do not cover all Types of Protection but give some advice and will be supplemented in the next edition.	
A.2	**General**

Schedule Drawings, which support the certificate of the Ex Product, may provide conditions for the particular Type of Protection. All markings should be in accordance with schedule drawings.
For enclosures and other components forming part of the enclosure and for fans, fan hoods and ventilation screens, the manufacturer should verify the material composition (e.g. External Provider's Declaration of Conformity, see Annex C).
Statistical bases are not appropriate for routine tests required by the certificate, except where the following currently permit such techniques:
• the relevant standard; or
• appropriate interpretation and clarification sheets;
All measurements should consider temperature variations.

Clause	Requirement	Documents or Comments	Verdict
A.3	**Ex d – Flameproof enclosures covered by IEC 60079-1**		
A.3.1	**Verification**		
Verification consists of a visual inspection and/or measurement. The measurement should be done with suitable measuring equipment. The persons doing this measurement should have the competence and knowledge of using this measuring equipment.		Visual inspection and random sampling with measurements. 100 % end test for each unit.	**P**
A.3.2	**Castings**		
Castings should be subject to verification that demonstrates conformity, e.g.: a) 100 % visual inspection should be done on each part; b) wall thickness (including those parts not subject to machining); c) flaws, inclusions, blow holes and porosity (by either a visual or test method depending upon the criticality). NOTE: Verification can be accomplished by 100 % visual inspection, or by another means deemed appropriate based on the ability of the manufacturer to effectively control production. Recovery of porous castings by impregnation methods, e.g. silicone is not permitted. In the event that a casting is recovered by welding it will become subject to the requirements applicable to welded enclosures, e.g. routine pressure testing.		Delegated to manufacturer of enclosures.	**P**
A.3.3	**Machining**		
Machining should be subject to verification by either 100 % inspection or statistical techniques as appropriate that demonstrates conformity, e.g. the following should be verified: a) flatness of flanged flamepaths; b) surface roughness of non-threaded flamepaths; c) fit of all threaded flamepaths (e.g. threaded entries and threaded access covers); d) depth of drilling and tapping of blind holes to ensure adequate residual wall thickness; e) dimensional requirements of all flamepaths. NOTE: Suitable statistical techniques are used in ISO 2859-1, ISO 3951-1 or equivalent standard.		Delegated to manufacturer of enclosures.	**P**
A.3.4	**Cemented joints and potted assemblies**		
Documented procedures should address the following, as applicable: a) shelf life and storage of cement, potting compounds; b) mixing; c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion); d) application e.g. filling instructions, freedom from voids and temperature conditions; e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period; f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process		Cemented joints with silicon only, visually verified.	**P**

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and the potted assembly, this could be for example using statistical techniques.			
A.3.5	**Routine overpressure testing**		
A.3.5.1	**General**		
The purpose of the test is to check that the enclosure does not suffer damage or permanent deformation. Leakage through cemented joints or potted assemblies would constitute a failure unless otherwise permitted by the issuer of the certificate. The test can be a single test conducted on a complete assembly, or a series of tests on each sub-assembly or component part. For the static routine overpressure test, it is sufficient to test the enclosure empty. The individual parts of a flameproof enclosure (for example, cover and base) can be tested separately. For enclosures that contain more than one discrete compartment, each compartment should be tested individually. The method used should ensure that the assembly, sub-assembly or component parts are subjected to representative stress patterns e.g. actual fastening facilities are used. Clamping that affects the mechanical properties of the Type of Protection would invalidate the test results. Due to safety considerations and difficulty in detecting leakage, hydraulic rather than pneumatic methods are recommended.		Enclosure certified with 4 x reference pressure. No routine tests.	**N/A**
A.3.5.2	**Batch testing**		
Where permitted by the certificate, the routine overpressure testing may be replaced by a batch test according to the following criteria, based on ISO 2859-1; a) For a production batch up to 100, a sampling of 8 should be tested at 1,5 times the reference pressure with no failures. b) For a production batch from 101 to 1 000, a sampling of 32 should be tested at 1,5 times the reference pressure with no failures. c) For a production batch from 1 001 up to 10 000, a sampling of 80 should be tested at 1,5 times the reference pressure with no failures. d) Batches above 10 000 should be subdivided into smaller batches. If there are any non-compliant test results,100 % of all remaining samples in the batch should be tested at 1,5 times the reference pressure. Future batches should be routine tested at 1,5 times the reference pressure until confidence is established to reconsider batch testing. NOTE: Upon non-compliant test results, reconsideration of this batch testing approach is at the discretion of the party issuing the certificate.		Enclosure certified with 4 x reference pressure. No routine tests.	**N/A**
A.3.5.3	**Welded construction**		
Where permitted by the certificate, the routine overpressure testing may be replaced by one of the following inspection methods: a) radiographic weld inspection; or b) ultrasonic weld inspection; or c) magnetic particle weld inspection; or d) liquid penetrant weld inspection. NOTE: ISO standards exist for each of the above weld inspection methods.		No welded construction.	**N/A**
A.3.6	**Flanged joints**		
Flanged joints should be verified after final assembly to ensure the gap specified in the Schedule Drawings is not exceeded. If not practical, special measure should be taken during the production.		No flanged joint.	**N/A**
A.3.7	**Elements, with non-measurable paths, of breathing and draining devices**		
For products containing elements like sintered metal, pressed metal wire or metal foam, see Annex B.		No such elements.	**N/A**

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A.4	**Ex i – intrinsic safety covered by IEC 60079-11**		
A.4.1	**Components for intrinsically safe products**		
	The following features should be verified with respect to the following components for use in intrinsically safe apparatus and associated apparatus. This normally means verifying the marking on the components or packaging and may be achieved by using statistical techniques where appropriate, as shown in Table A.1:	Safety relevant items ordered with detailed product information.	**P**
	Table A.1 Component features requiring compatibility		
Resistors: value, power, type, tolerance, case size		Regarded	**P**
Capacitors: value, tolerance, type, rated voltage, case size		No such components	**N/A**
Piezo-electric devices: manufacturer, type, capacitance		No such components	**N/A**
	Inductive components: type, inductance, DC. resistance, number of turns, wire gauge and material, material specification of core and bobbin where appropriate	Regarded	**P**
Transformers: type, manufacturer, isolation, voltage		No such components	**N/A**
Optical isolators: Optical isolator type, isolation, voltage		No such components	**N/A**
Semiconductors:	– Transistors – Integrated circuits – Thyristors – Diodes – Zener diodes type number, power value and where appropriate, the manufacturer	Regarded	**P**
Cells and batteries: manufacturer and type number, or IEC designation		No such components	**N/A**
Fuses: manufacturer, type, value		No such components	**N/A**
Insulating materials: specification, dimensions and where appropriate type number		No such components	**N/A**
Connectors (e.g. plugs/sockets and terminals): type number and where appropriate, the manufacturer		Regarded	**P**
A.4.2	**Printed circuit boards (PCB)**		
A.4.2.1	**Non-populated PCBs**		
PCBs may be accepted with a declaration of conformity (see Annex C). The declaration should state compliance to the purchase documents e.g. a quality plan that lists the factors that together demonstrate conformity of the product. For simple single- or double-sided PCBs, the copper artwork may be visually verified using photographic negative (transparency), certified drawing or controlled inspection samples. Purchase documents should specify copper thickness with tolerances, PCB thickness with tolerances and CTI values.		Only populated PCB's from own KUK Electronic. See also clause 8.4.1.	**N/A**
A.4.2.2	**Populated PCBs**		
• Varnish and coatings should be controlled with respect to the specification of material and effectiveness of the application. • Documented procedures should ensure that the application of varnish and coatings are in conformity with the certificate and/or schedule drawings. • For PCBs the manufacturer should maintain a list of safety critical components used in production (e.g. resistors and Zener diodes) determined during Ex Equipment assessment. The safety critical components placed on the PCB should be verified on a 100 % basis. • Specified distances and clearances on manually assembled PCBs should be verified on a 100 % basis. • This may be conducted by one of the following methods:		Ex-PCB's assembled with protective diode, resistor and mosfet. The PCB's are produced by KUK Electronic. A conformity statement will be delivered. Suppliers are evaluated and assessed as required.	**P**

Clause	Requirement	Documents or Comments	Verdict
a) a visual verification; b) for surface mount components, by ensuring correct loading of the "pick and place" machines and a visual verification of correct placement; c) by automatic test equipment (ATE) if the ATE addresses each individual safety critical component and by a visual verification conducted to verify type number of components in shunt Zener diode/diode assemblies. • Where the surface mount component "pick and place" machine selects the component reel based on measuring the component value the measuring function should be calibrated. • Documented procedures should be provided that ensure that workmanship standards are defined with respect to component mounting and soldering. • Documented procedures should ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area and insulation thickness are in conformity with the schedule drawings.			
A.4.3	**Sub-assemblies and assemblies**		
Documented procedures should ensure that production documentation includes all relevant variations to the product design. Production documentation should address all safety critical components, and in the case of encapsulated parts, the compound manufacturer, type, mix and minimum depth. Documented procedures should address the following: a) shelf life and storage of cement and potting compounds; b) mixing; c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion); d) application e.g. filling instructions, freedom from voids and temperature conditions; e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period; f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process and the potted assembly, this could be for example using statistical techniques. Documented procedures should also ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area, insulation thickness and labels (where appropriate) are fitted. Sealing arrangements should be verified for compatibility with the product's ingress protection rating.		PCB is the only sub-component	**P**
A.4.4	**Enclosures for Group III or reduced spacing**		
For intrinsically safe apparatus for Group III, or for apparatus that relies on the enclosure for reduced spacing, demonstration of the conformity of the enclosure with the schedule drawings should include the following: a) depths of bore holes and tap holes; b) dimensional requirements for those enclosure parts relevant for sealing effectiveness or mechanical stability; c) insulating coatings and surface conditioning; material, layer thickness. Documented procedures should address the following: a) the gaskets correspond to the quoted specification;		PCB is a component for the final solenoid which is assembled by a certified supplier => Quality system EN ISO/IEC 80079-34.	**P**

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b) the sealing elements' effectiveness, e.g. by checking the sealing elements' correct fit. If a gasket's correct fit becomes apparent only after assembly, the imprint could be visually examined, e.g. by use of adequate methods such as use of chalk.			
A.4.5	**Routine verifications and tests**		
Procedures for all routine verifications and tests specified in the schedule drawings should be reviewed, along with the results of those verifications and tests, e.g. high voltage tests on complete assemblies or individual components such as transformers, should be controlled by documented procedures and conducted on a 100 % basis unless otherwise permitted.		The required routine tests according to the certificates will be performed. After each production step, in-circuit tests are carried out if necessary. 100% end test.	**P**
A.4.6	**Intrinsically safe circuits and assemblies incorporated in Ex equipment of other types of protection**		
Where Ex equipment contains intrinsically safe circuits then precautions should be taken as stated in the certificate to ensure that other items listed in the certificate are selected, mounted and installed in accordance with schedule drawings.		Regarded	**P**

Clause	Requirement	Documents or Comments	Verdict
A.5	**Ex e – Increased safety covered by IEC 60079-7**		
A.5.1	**Ingress protection (IP)**		
Documented procedures should ensure that the following is verified: a) weld continuity; b) fitting of gaskets and seals; c) continuity of moulded grooves and tongues; d) application of cements including a visual inspection after curing.		Regarded Connection box is IP65 approved	**P**
A.5.2	**Internal wiring and contact integrity**		
Documented procedures should ensure that the following are verified: a) wiring is clamped as specified in the schedule drawings; b) wiring is terminated as specified in the schedule drawings; c) wires are as specified in the schedule drawings; d) connections are tightened as specified in the schedule drawings; e) creepage distances and clearances are as specified in the schedule drawings and have not been compromised.		Internal wiring fixed, cannot move.	**P**
A.5.3	**Rotating machines**		
Documented procedures should ensure that the following are verified: a) rotor end connections and fixing bars are as specified in the schedule drawings; b) the fabrication process for die-cast rotors is as specified in the schedule drawings; c) production controls are in place for: – the air gap (rotor to stator) as specified in the schedule drawings; – the fan clearance as specified in the schedule drawings; – the bearing seal clearances as specified in the schedule drawings. NOTE: The schedule drawings might not specify a bearing seal clearance as not all Levels of Protection require a bearing seal clearance for all bearing seal designs.		No such machine.	**N/A**
A.5.4	**Windings**		
Documented procedures should ensure that the following are verified: a) wire and insulation system are as specified in the schedule drawings;		Regarded	**P**

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b) the impregnations process is as specified in the schedule drawings; c) insulation materials are as specified in the schedule drawings; d) mechanical securing of conductors are as specified in the schedule drawings; e) type and mounting of protective devices (e.g. thermal cut-outs) are as specified in the schedule drawings.			
A.5.5	**Terminal boxes**		
Documented procedures should ensure that the following are verified: a) terminals are as specified in the schedule drawings; b) creepage distances and clearances as specified in the schedule drawings have not been compromised.		Regarded Terminals fixed, cannot move.	**P**
A.5.6	**Cable Glands, terminals and other accessories**		
The dimensions specified in the schedule drawings should be confirmed on a statistical basis. Where entry openings are secured by non-Ex temporary plugs (e.g. for transport only), additional information should be provided.		Only separately certified cable glands used.	**P**
A.5.7	**Routine verifications and tests**		
Procedures for all routine verifications and tests specified in the schedule drawings should be reviewed, along with the results of those verifications and tests.		100 % incl. high-voltage tests	**P**

Clause	Requirement	Documents or Comments	Verdict
A.7	**Ex m – Encapsulation covered by IEC 60079-18**		
A.7.1	**Production documentation**		
Thermal protection (e.g. thermal fuses) should be positioned according to and be of the type specified in the schedule drawings. Documented procedures should address the following: a) shelf life and storage of cement, potting compounds; b) mixing; c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion); d) application e.g. filling instructions, freedom from voids and temperature conditions; e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period; f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process and the potted assembly, this could be for example using statistical techniques.		Regarded Potting under vacuum for Ex “d” solenoids or complete solenoids delivered by certified supplier and branded for Eugen Seitz => Supplier has Quality system EN ISO/IEC 80079-34.	**P**
A.7.2	**Routine verifications and tests**		
All tests should be documented. Typical tests include: a) visual examination; b) dielectric strength test.		Regarded	**P**

A.10	**Equipment covered by IEC 60079-15**		
A.10.1	**General requirements**		
A routine dielectric strength routine test needs to be performed for all devices and equipment in accordance with IEC 60079-15		Regarded	**P**
A.10.2	**Ex nA – Non-sparking equipment**		
A.10.2.1	**Circuit boards (PCBs)**		
Documented procedures should ensure that the following are verified:		No PCB use on this protection.	**N/A**

a) the CTI, board and copper thickness of single and multi-layer boards is as specified in the schedule drawings and that declarations are received from the supplier; b) populated PCBs are populated correctly, and declarations received from the supplier, if applicable; c) conformal coatings used to reduce spacing requirements are those specified in the schedule drawing by inspection or declaration from supplier. d) These verifications can be performed by inspection when it is possible or PCBs may be accepted with a declaration of conformity (see Annex C). The declaration should state compliance to the purchase documents			
A.10.2.2	**Terminals and internal wiring**		
Documented procedures should ensure that the following are verified: a) terminals are those specified in the schedule drawings; b) creepage and clearance distances are as specified in schedule drawings; c) wire is the type specified in the schedule drawings and that segregation (where required) is maintained.		Regarded Certified glands use.	**P**
A.10.3	**Ex nC – Sealed devices**		
Documented methods should ensure the following examinations: a) That creepage distances and clearances should be confirmed on a statistical basis. b) The sealing requirements specified in the schedule drawings should be confirmed on a statistical basis.		No such protection	**N/A**
A.10.4	**Ex nR – Restricted Breathing**		
A.10.4.1	**General requirements**		
Documented procedures should ensure that the following are verified: a) creepage distances and clearances of integrated devices, as specified in the schedule drawings, are not affected; b) the dimensions specified in the schedule drawings are confirmed (statistical method may be used only if permitted – see 8.6).		No such protection	**N/A**
A.10.4.2	**Cable glands**		
Documented methods should ensure that it is clearly distinguished in the schedule drawings which types of Cable Glands are associated with the enclosure forming a unit or being particularly matched and hence are subjected to the routine test of the enclosure.		No such protection	**N/A**
A.10.4.3	**Plunger actuators, shafts and axles**		
Documented methods should ensure that no lubricants or similar materials are used prior to the routine test.		No such protection	**N/A**
A.10.4.4	**Test equipment**		
Documented methods should ensure the correct assembling and function of test equipment.		No such protection	**N/A**
A.10.4.5	**Routine tests**		
All routine tests including procedure and records should be documented. These are basically pressure tests for restricted-breathing enclosures and electronic starter and ignition devices.		No such protection	**N/A**

Clause	Requirement	Documents or Comments	Verdict
A.11	**Ex t – Dust ignition protection by enclosure covered by IEC 60079-31**		
A.11.1	**Casting**		
Castings should be subject to verification that demonstrates conformity with the schedule drawing, e.g.: a) wall thickness (including the non-machinable parts); b) cracks, inclusions, bubbles and porosity.		Regarded Visual inspection for casting enclosures	**P**

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Clause	Requirement	Documents or Comments	Verdict
A.11.2	**Enclosure parts**		
Enclosure parts should be subject to verification that demonstrates conformity with the schedule drawing, e.g.: a) depths of bore holes and tap holes; b) dimensional requirements for those enclosure parts relevant for sealing effectiveness or mechanical stability; c) insulating coatings and surface conditioning; material, layer thickness.		Potted plastic enclosure	**P**
A.11.3	**Gaskets**		
Documented procedures should address the following: a) the gaskets correspond to the quoted specification; b) the sealing elements' effectiveness, e.g. by checking the sealing elements' correct fit. If a gasket's correct fit becomes apparent only after assembly, the imprint could be visually examined, e.g. by use of adequate tools such as chalk.		Gasket and working instruction defined.	**P**
A.11.4	**Protection devices**		
Protection devices should be subject to verification that demonstrates conformity with the schedule drawings. Wherever protection devices (e.g. thermal safety devices) are specified in the certificate, they should be verified according to type and placement.		Regarded	**P**
A.11.5	**Cemented and cast enclosure parts**		
Documented procedures should address the following: a) shelf life and storage of cement, potting compounds; b) mixing; c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion); d) application e.g. filling instructions, freedom from voids and temperature conditions; e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period; f) after curing, 100% visual inspection should be done on each assembly.		Same procedure as for “Ex m”	**P**
A.11.6	**Ingress protection (IP)**		
Documented procedures should ensure that the following is verified: a) weld continuity; b) fitting of gaskets and seals; c) continuity of moulded grooves and tongues; d) application of cements including a visual inspection after curing.		Regarded Visual inspection and working instructions	**P**
A.11.7	**Routine verifications and tests**		
All tests should be documented. Typical tests include: a) the visual inspection; b) further verification and test requirements can result from the concepts of the dusts explosion protection standards. However, these can essentially be derived from the requirements for the types of protection listed so far.		Regarded	**P**

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4. List of certificates relating to IECEx/ATEX QAR

IECEx Certificate No.	Issue	Date	Description of Ex equipment	Ex marking
IECEx PTB 20.0011X	0	2020-03-23	Solenod type 14F52	Ex eb mb IIC T6, T4 Gb Ex tb mb IIIC T80 °C, T130 °C Db
IECEx EPS 18.0055X	0	2018-09-05	Ex solenoid coils type 2F86	Ex mb IIC 150 °C (T3) Gb
IECEx IBE 14.0079X	0	2014-12-04	Solenod type 2E85	Ex nA IIC T3 Gc

ATEX Certificate No.	Issue	Date	Description of Ex equipment	Ex marking
PTB 99 ATEX 2146	1	2013-09-17	Magnetventil Typ 12F73 Ci…	II 2G EEx ia IIC T6, T5
PTB 00 ATEX 2030	1	2013-09-18	Magnetventil Typ PV 12F73 Xi…	II 2G Ex ia IIC T5 or T6 II 2D Ex ia IIIC T100 °C or T80 °C
PTB 00 ATEX 2211 X	3	2007-07-11	Magnetspule Typen 2.52; 2.53, 2.54, 2.55	II 2G Ex emb II T4/T5/T6 II 2D Ex tD A21 IP65 T80 °C, T95 °C, T130 °C
PTB 01 ATEX 2020	5	2013-07-17	Magnetspule Typ 11G52	II 2G Ex ib IIC T5 or T6 Gb II 2D Ex ib IIIC T95 °C or T80 °C Db
PTB 01 ATEX 2129 X	3	2005-04-15	Magnetspulen Typ 2A52W, 2C52W	II 2G EEx em T4 or T6 II 2D IP65 T110 °C or T80 °C
PTB 02 ATEX 2125 X	3	2012-07-31	Magnetspule Typ 11A52, 11C52, 11E52, 11F52	II 2G Ex eb mb IIC t6, T5 II 2D Ex tb IIIC t80 °C, T95 °C
PTB 05 ATEX 2050 X	3	2013-05-22	Ventilmagnet Typ 14C80, 14A80	II 2G Ex mb IIC T6, T5, T4 Gb II 2D Ex mb tb IIC T80 °C, T95 °C, T130 °C Db
PTB 12 ATEX 2024 X	0	2012-10-11	Magnetspule Typ 14F52	II 2G Ex e mb IIC T4, T6 Gb II 2D Ex tb mb IIIC t130 °C, T80 °C Db
KEMA 02 ATEX 2037	2	2010-03-05	Magnetspule Typen 11A53, 11C53, 11E53, 11F53	II 2G Ex e mb II T6 II 2D Ex tD A21 Ip65 T70 °C
BVS 14 ATEX E011	1	2015-09-28	Magnetspule Typ 2.6.W	II 2G Ex db IIC T* Gb II 2D Ex tb IIIC T* °C Db
BVS 15 ATEX E105	0	2015-09-21	Magnetspule Typ 2.5., 2.5.W	II 2G Ex eb mb IIC T* Gb II 2D Ex tb IIIC T* °C Db

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ATEX Certificate No.	Issue	Date	Description of Ex equipment	Ex marking
EPS 18 ATEX 1098 X	0	2018-09-05	Ex Magnetkörper 2F86…	II 2G Ex mb IIC 150 °C (T3) Gb
PTB 06 ATEX 1062 X	0	2006-12-12	Elektromagnet Type 25-15-xx-yy-150 Type 25-15-xx-yy-165	II 2G EX d IIC 150 °C bzw. 165 °C
PTB 06 ATEX 1063 X	0	2006-12-12	Elektromagnet Type 160-15-xx-yy-140 Type 160-15-xx-yy-155	II 2G EX d IIC 150 °C bzw. 165 °C

Date: 21.08.2020 Sign: 

5. Audit non-conformities and observations *No mandated format required*

No	Date	**Non-conformities** (ref clause and standard)	Customer response	Lead auditor acceptance	Closed
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No	Date	**Observations** (ref clause and standard)
1.	2020-09-15	**Requirement**: EU-Declaration of conformity **Observation:** The EU-Declaration of conformity should be uniformly structured for all certificates. EU-Declarations of conformity for certificates with expired standards should contain the information that a gap analysis has been made to the current standard status. For IECEx certificates no EU-Declaration of conformity is required