eurofins | E&E	**IECEx QUALITY ASSESSMENT REPORT**	IEC IECEx Ex
Report No.:	**20CH-01412.X07**	**QAR No.: CH/SEV/QAR16.0001/06**

Project No.	**20CH-01412OR04**			
Ex QMS Certificates	**SEV 16 ATEX 4130**			
Manufacturer Include Address with post code	Wandfluh Hydraulik + Elektronik AG Helkenstrasse 13 3714 Frutigen SWITZERLAND			
Production Site(s) audited Include Address with post code	Wandfluh Hydraulik + Elektronik AG Helkenstrasse 13 3714 Frutigen SWITZERLAND			
Product Description	Hydraulics and Electronics whole company			
Employee count	Total onsite: 264 Total involved in Ex products: 30			
Scope of Audit	Initial Assessment ☐ Re-Assessment ☒		Surveillance Assessment ☐ Special Assessment ☐	
Scheme	IECEx ☒	ATEX ☒		
Ex equipment with type(s) of protection	d ☒ e ☐ h ☐ i ☒ m ☐ n ☐ p ☐ t ☒ op ☐ q ☐			
Audit Team Leader	Thomas Köhntopp			
Audit Date	2023-09-12			

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 Directive 2014/34/EU annex IV fulfilled.
NO nonconformities listed.

Issuing of the ATEX QAN is recommended.

Next Quality Audit due : September 2023

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):	**0**
OBS	**1**

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.

2023-09-12
Audit Team Leader Signature

2023-09-13
ExCB 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

: 2023-09-12, 1 day assessment with one auditor

2.4 Certified Quality System

ISO 9001 Certificate No	Certified by	Expiry date	Scope
10632	SQS	2024-03-10	Entwicklung, Herstellung und Verkauf sowie Handel von Hydraulikkomponenten, Hydrauliksystemen, dazugehörender Elektronik

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.

At Wandfluh Hydraulik + Elektronik AG the last surveillance audit took place on 2023-02-08. No non-conformities are listed.

2.5 Composition of Audit Team:

Name	Position	Role in Audit *(Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)*
Thomas Köhntopp	QAR Auditor	Sole Auditor
Munira Gamma	Technical Reviewer	Certification Manager

2.6 Interviewed Representatives of Manufacturer (Auditee):

Name	Position
Tobias Krause	Head of Technology, Ex authorized person
Harris Elayathamby	Head of Management System
Mike Zürcher	Industrial Equipment TE (planned as deputy Ex authorized person)

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
Roth Décolletage AG	Mechanical components

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
01	Zertifikat ISO 9001:2015	---	2021-03-13
02	Organigramm	---	2023-08-31
03	Auditbericht Seite 7 SQS 2023	---	2023-02-20
04	Beauftragte der Leitung 2022	---	2023-08-22
05	Bericht der Ex-Schutz-Verantwortlichen 2022	---	2023-03-27
06	Technical description MKY45	05	2021-03-23
07	Installations- und Betriebsanleitung MKY45	---	Ed. 22 10
08	Installations- und Betriebsanleitung MKZ45	---	Ed. 22 10
09	Schulung Explosionsschutz	---	2021-12-10
10	Arbeitsanweisung Magnetspule MDZ	02	2019-03-25
11	Montageanweisung Magnetspule MKY45	27	2022-10-11
12	Weisung Ex-Schutz	---	2023-08-17
13	Lieferantenmanagement	---	2022-02-08
14	Lieferantenselbstauskunft	---	2019-03-01
15	Certificate of Calibration 2212061602 - Keithley 2495	---	2022-12-09
16	Kallibrierprotokoll Gewindelehrdorn	---	2020-02-21

2.9 Audit report history

QAR-Revision	Description	Issue date	QAN
CH/SEV/QAR16.0001/00	Initial Assessment Electrosuisse: 16-Ex-0021.01	2016-04-26	SEV 16 ATEX 4130
CH/SEV/QAR16.0001/01	Correction of the assessment Report. Electrosuisse: 16-Ex-0021.02	2016-07-22	
CH/SEV/QAR16.0001/02	Initial Assessment Eurofins Electrosuisse: 17-Ex-0089.X01	2017-10-26	SEV 16 ATEX 4130
CH/SEV/QAR16.0001/03	Surveillance Assessment Eurofins Electrosuisse: 17-Ex-0089.X02	2019-04-10	
CH/SEV/QAR16.0001/04	Re-Assessment Eurofins E & E: 20CH-01412.X05	2020-10-14	SEV 16 ATEX 4130 Issue 1
CH/SEV/QAR16.0001/05	Surveillance Assessment Eurofins E & E: 20CH-01412.X06	2022-04-20	
CH/SEV/QAR16.0001/06	Re-Assessment Eurofins E & E: 20CH-01412.X07	2023-09-13	SEV 16 ATEX 4130 Issue 2

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.		Quality goals and quality policy put a focus on the ex-certified products. A new web based quality management software SynoNet 23.0 was integrated. The software is very clear and you can access the documents with just a few clicks. A new ERP system is to be introduced in November. *See attached documents:* *Doc. No. 04 - Doc. No. 06*	**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 techical documentation. *Document reviewed:* *Doc. No. 01 - Doc. No. 05*	**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). *Document reviewed:* *Doc. No. 01 - Doc. No. 03*	**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). *Document reviewed:* *Doc. No. 01 - Doc. No. 05*	**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). *Document reviewed:* *Doc. No. 01 - Doc. No. 05*	**P**

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Clause	Requirement	Documents or Comments	Verdict
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:			**P**
a) the effective co-ordination of activities with respect to Ex Products;		Mr Tobias Krause as the responsible person for several years and coordinates all Ex relevant activities for components. *Document reviewed:* *Doc No. 02 and 05*	**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. *Document reviewed:* *Doc No. 12*	**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 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.		Changes of the quality system are reported to the certification body. *Document reviewed:* *Doc No. 12*	**P**
d) the authorization of initial approval and changes to related drawings, where appropriate;		Product changes have to be approved by the Ex responsible person. *Document reviewed:* *Doc No. 12*	**P**
e) the authorization of concessions (see 8.7 f));		Concessions need authorization of Ex authorized person.	**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 authorized person. *Document reviewed:* *Doc No. 12*	**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 authorized person is involved into the manufacturing process. Only one manufacturing site.	**P**
Records demonstrating this shall be available and be maintained as documented information.		All records 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).	**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**

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Clause	Requirement	Documents or Comments	Verdict
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. The calibration certificate shall meet one of the following requirements:		Each measuring equipment has its own number and is traced by a software tool. The equipment is calibrated internal and external in accredited Calibration Labs. *Document reviewed:* *Doc. No. 15,16*	**P**
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.		The calibration certificate has no logo and contains the required information according to b). *Document reviewed:* *Doc. No. 15,16*	**N/A**
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.		The calibration certificate has no logo and contains the required information according to this clause. *Document reviewed:* *Doc. No. 15,16*	**P**
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).		The calibration certificate has no logo and contains the required information according to b).	**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).	**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,		Training plan and knowledge matrix for each person available. For people involved with certified products training is	**P**

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Clause	Requirement	Documents or Comments	Verdict
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.		done by the Ex-responsible person each year. *Document reviewed:* *"Kompetenzmatrix" as Excel file.*	
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.		Due to the flat hierarchy, short communication paths between the different departments.	**P**
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).	**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;		Drawings for Ex-components are accordingly marked. Changes have to be approved by Ex authorized person.	**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;		Changes have to be approved by Ex authorized person. The development software has a system for release of drawings	**NC1**
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.	**P**
d) there shall be a documented system that refers all related drawings to the relevant schedule drawings;		System is in place.	**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;		Drawings for Ex-components are accordingly marked. *Document reviewed:*	**P**

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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.		*Sample drawings for the MKY solenoid.*	
g) the manufacturer shall document the body responsible for the verification of the quality management system of each certificate; 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.		System is in place.	**P**
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;		Checked every year. Documented in an Excel file. Process is defined.	**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 required quality records are electronically stored and available 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.	Confirmed 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.		Ex-relevant aspects are checked by the Ex-authorized person.	**P**

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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.			
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, quality management system or marketing documents) that could affect Ex Product compliance.		Possible changes have to be approved by the Ex responsible person.	**P**
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 not subcontracted.	**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. The supplier selection and supplier evaluation was checked based on the Roth Décolletage AG. *Document reviewed:* *Doc. No. 13,14*	**P**
2) where the features affecting the Type of Protection cannot be verified at a later stage or are not verified by the manufacturer		No such kind of products.	**N/A**

Clause	Requirement	Documents or Comments	Verdict
	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, – the body responsible for the verification of the quality management system performs periodic audits at the external providers.		
	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;	All external providers are checked once a year. *Document reviewed:* *Doc. No. 13*	**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.	All external providers are checked once a year.	**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,	Regarded, process in place.	**P**

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	product or service is required, if a declaration of conformity is supplied for each batch or product;		
	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 the external provider e.g. by a declaration of conformity including test results, if required;	Regarded, process in place.	**P**
	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;	Not used for the product.	**N/A**
	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;	Not used for the product.	**N/A**
	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**

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Clause	Requirement	Documents or Comments	Verdict
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. Specification documents will be sent with the order.	**P**
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;		Not used for the product.	**N/A**
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;		Purchase information includes Ex- statements where applicable.	**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.		Not used for the product.	**N/A**
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;		Each product has his own name plate with production, position number and manufacturing date. Traceability is, back to the components, 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.		Each product has his own name plate with production, position number and manufacturing date. Traceability is, back to the components, 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.		No such orders accepted.	**N/A**
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**

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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.		Each product will be end tested and results are stored in the IT system or as paper document. Name plate is attached after end test.	**P**
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.		Each product will be delivered with complete instruction manual. Test are documented and signed.	**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 subsidiary company or distributor. 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;		All required quality records are electronically stored and available for at least 10 years.	**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, no such concessions permitted.	**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**

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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.		Regularly internal audits ensure Ex-compliant products. An internal audit is done every year at the manufacturing location. **OBS1: The checklist column Result should always be filled in with a remark and not be empty.** *Document reviewed:* *Doc. No. 05*	**OBS1**
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.		Recommended but 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.		A management review takes place once a year. The management report of the year 2022 is reviewed online during the audit. Mr Krause as ex-responsible person creates a separate report for Ex relevant products. *Document reviewed:* *Doc No.05*	**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.	Nonconformities and the results of the corrective action are tracked.	**P**
10.2	**Nonconformity and corrective action** 10.2 of ISO 9001:2015 applies.	Nonconformities and the results of the corrective action are tracked.	**P**

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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**

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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**		**P**
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 on each working step. Important dimensions of each enclosure measured by a Scanning platform. All relevant persons are appropriately trained	**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.		No castings.	**N/A**
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;		Testing of housing with calibre and coordinate measuring equipment.	**P**

Clause	Requirement	Documents or Comments	Verdict
e) dimensional requirements of all flamepaths. NOTE: Suitable statistical techniques are used in ISO 2859-1, ISO 3951-1 or equivalent standard.			
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 and the potted assembly, this could be for example using statistical techniques.		Potting is done according working instruction with potting equipment. Document reviewed: Doc No.11	**P**
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.		The potted joints are checked visual on checkpoints on each unit. Document reviewed: Doc No.11	**P**
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.		No routing overpressures testing.	**N/A**

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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 constructions.	**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 joints.	**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 components.	**N/A**

Clause	Requirement			Documents or Comments	Verdict
A.4	**Ex i – intrinsic safety covered by IEC 60079-11**				
A.4.1	**Components for intrinsically safe products**				**P**
	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:			Unit is considered intrinsically safe based on the construction of the unit. See Table A.1 below.	**P**
	Table A.1 Component features requiring compatibility				**P**
Resistors: value, power, type, tolerance, case size				No such components	**N/A**
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**

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Clause	Requirement	Documents or Comments	Verdict
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.		Relevant information included in purchase orders via ERP system	**P**
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: 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.		Encapsulation process defined and verified. Simple PCB populated with diodes. PSB is potted in a steel enclosure. Visual verification. Document reviewed: Doc No.10	**P**
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);		No such assemblies.	**N/A**

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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.			
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; 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.		See 4.2.2	**P**
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.		100% End test according to defined procedures.	**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.		No such product.	**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);		No castings.	**N/A**

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b) cracks, inclusions, bubbles and porosity.			
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.		Testing of housing with calibre and measuring equipment.	**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.		Possible gaskets according to specifications and visually checked during manufacturing process.	**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.		No protection devices.	**N/A**
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.		Potting is done according working instruction with potting equipment.	**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.		Visually checked during manufacturing.	**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.		Visual inspection on finished product. Test results are documented and stored in ERP system.	**P**

4. List of certificates relating to IECEx/ATEX QAR

4.1 IECEx CoC:

IECEx Certificate No.	Issue	Date	Description of Ex equipment	Ex marking
IECEx BVS 11.0018X	02	2021-05-20	Solenoid type MKY45/18x60-**-**-*#*	Ex db I Mb Ex db IIC T6/T4 Gb Ex tb IIIC T80°C/T130°C Db
IECEx ITA 12.0027X	01	2016-08-18	Solenoid type MKY45/18x60-..-L.-.	Ex d IIC T6 or T4 Gb Ex tb IIIC T80 °C or T130 °C db IP65 Ex d I Mb
IECEx SEV 16.0005X	01	2021-09-28	Solenoid coil type M*Z45-***-***	Ex ia I Ma Ex ia IIC T5 Ga Ex ia IIC T6 Ga

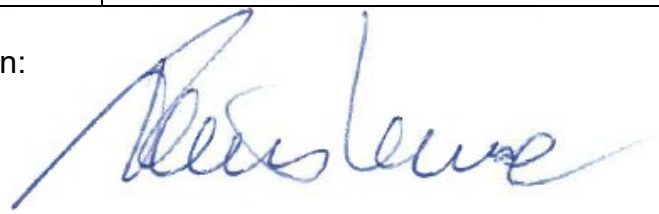
4.2 EU-Type Examination Certificate:

ATEX Certificate No.	Issue	Date	Description of Ex equipment	Ex marking
BVS 11 ATEX E 037 X	02	2021-05-17	Magnetspule type MKY45/18x60-**-**-*#*	Ex db I Mb Ex db IIC T6/T4 Gb Ex tb IIIC T80°C/T130°C Db
SEV 16 ATEX 0127 X	01	2021-09-28	Solenoid coil type M*Z45-***-***	I M1 Ex ia I Ma II 1G Ex ia IIC T5 Ga II 1G Ex ia IIC T6 Ga

4.3 UKCA:

ATEX Certificate No.	Issue	Date	Description of Ex equipment	Ex marking
CML 22UKEX1157X	0	22 Mar 2022	Magnetspule type MKY45/18x60-**-**-*#*	Ex db I Mb Ex db IIC T6/T4 Gb Ex tb IIIC T80°C/T130°C Db
CML 22UKEX2141X	0	10 Mar 2022	Solenoid coil type M*Z45-***-***	I M1 Ex ia I Ma II 1G Ex ia IIC T5 Ga II 1G Ex ia IIC T6 Ga

Date: 2023-09-12 Sign:



5. Audit non-conformities and observations

No	Date	**Non-conformities** (ref clause and standard)	Customer response	Lead auditor acceptance	Closed
NC1	2022-04-20	ISO/IEC 80079-34 Clause 5.3 d), 7.5.3 b) Some of the production drawings get new revision in the meantime. These were not reported to the certification body for review and filing.	A revision document (0299648) was created immediately (21.04.2022) and handed over to the certification body with the relevant documents for review.	The documents were checked and filed by the certification body. All changes are not Ex-relevant. At next extension of Certificate the documents will be added.	2022-04-28

No	Date	**Observations** (ref clause and standard)
OBS1	2023-09-12	ISO/IEC 80079-34 Clause 9.2 The checklist column Result should always be filled in with a remark and not be empty.