

	IECEX QUALITY ASSESSMENT REPORT	 
Report No.: 25.0003/00	QAR No.: FTZU QAR 25.0003	

Project No.	FTZU 25.0003/00 – 13.05.2025		
Ex QMS Certificates	FTZU 25 ATEX Q 004		
Manufacturer Include Address with post code	doublepower!! s.r.o. Bílková 856/18 110 00 Praha 1 Czech republic		
Locations audited Include Address with post code	doublepower!! s.r.o. Dubská 1011 272 03 Kladno Czech republic		
Product Description	Electrical devices (LED luminaires)		
Employee count	Total onsite: 34	Total involved in Ex products: 10	
Scope of Audit	Initial Assessment <input checked="" type="checkbox"/>	Surveillance Assessment <input type="checkbox"/>	
	Re-Assessment <input type="checkbox"/>	Special Assessment <input type="checkbox"/>	
Scheme	IECEX <input checked="" type="checkbox"/>	Spare <input type="checkbox"/>	Spare <input type="checkbox"/>
Ex equipment with type(s) of protection	d <input checked="" type="checkbox"/> e <input checked="" type="checkbox"/> i <input type="checkbox"/> m <input type="checkbox"/> n <input type="checkbox"/> o <input type="checkbox"/> p <input type="checkbox"/> q <input type="checkbox"/> s <input type="checkbox"/> t <input checked="" type="checkbox"/> v <input type="checkbox"/> op <input checked="" type="checkbox"/> c <input type="checkbox"/> b <input type="checkbox"/> k <input type="checkbox"/> Other (<i>specify</i>) <input type="checkbox"/>		
Audit Team Leader	Petr Šoltys		
Audit Date	13.05.2025		

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IECEX ExCB



FTZÚ, s.p.,
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716 07 Ostrava-Radvanice, Czech Republic



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1. Summary Report**Assessment Summary and Conclusions:**

Manufacturer for development and production of LED industrial luminaires.

Quality system is certified according to ISO 9001.

Company is certified according to EN ISO/IEC 80079-34 as FTZU 25 ATEX Q 004.

The requirements of EN ISO/IEC 80079-34:2020 were added to quality manual and relevant procedures. These requirements are fulfilled in company and in prepared production, it was verified by audit.

Next Quality Audit due : 5/2026

Non-Conformities

(Indicate the Serial No.(s) of non-conformities recorded. Individual non-conformities are recorded on the non-conformity report (F-002))

NCR No.(s): ---

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 ☒

EN ISO/IEC 80079-34:2020 (idt.) ☒

2.3 Date(s) and Duration of Audit : 1 day – 13.05.2025 + 1 day preparation

Include total number of auditor days on site

2.4 Certified Quality System

ISO 9001 Certificate No	Certified by	Expiry date	Scope
17.169.187	TUV SUD	23.02.2028	Development, production and installation of industrial luminaires.

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.

2.5 Composition of Audit Team:

Name	Position	Role in Audit (Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)
Petr Soltys	Auditor	Sole Auditor

2.6 Interviewed Representatives of Manufacturer (Auditee):

Name	Position
Martin Laštůvka	PSK (Quality Manager)
Petr Frans	MV (Production Manager)
Matěj Hoffmann	MVV (Chef designer)



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Name	Position
Martin Hexner	CEO

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
AL-SOLID s.r.o.	Al castings, enclosure, machining
DNA CENTRAL EUROPE, s.r.o.	PCB boards
METAFO spol. s r.o.	Painting
SCHMACHTL s.r.o.	Cable entry, blind flange
M&D Elektro	Cable entry

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
PK01	Quality and Production Manual for Explosive Environments	1.0	12.12.2024
S01	Documented information management	1.0	1.7.2024
S02	Personnel management	1.0	1.7.2024
S03	Design and development management.	1.0	1.7.2024
S04	Production	1.0	1.9.2024
S05	Metrological order	1.0	12.11.2024
S06	Archiving rules	1.0	1.7.2024
WI03	Cap pouring procedure	1.0	20.4.2025
WI04	Output inspection procedure	1.0	29.4.2025
210 0000000000006	Operating, installation and maintenance instructions		25.3.2025
TBD	Casting and Inspection Procedures	1.0	TBD
WI06	Drawing and Manufacturing Documentation	1.0	23.4.2025



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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. *The IECEx System expectation is that where the form specifies that "ISO 9001:2015 applies" for the manufacturing of Ex product, these requirements are reviewed and assessed as necessary by the ExCB irrespective of whether the manufacturer has ISO 9001:2015 certification (guidance on ExMC decisions in this area is available in 17021-1, Clause 9.1.3.4)*

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 reference and/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 organizational context is available and 1x per year, at the management review of 20.1.2025, see requirement 9.3	P
4.2	Understanding the needs and expectations of interested parties 4.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
4.3	Determining the scope of the quality management system 4.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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.	doublepower has defined risks for processes as part of the context of internal and external aspects, see risk analysis, review 1x per year. The output is reported to the company, see 9.3	P
5.1.1	General 5.1.1 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
5.1.2	Customer focus 5.1.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
5.2.1	Establishing the quality policy 5.2.1 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
5.2.2	Communicating the quality policy 5.2.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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;	The organization defines annual objectives, the	P



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		evaluation output is part of the management review. MVV coordinates activities regarding Ex products, The role is defined in PK01 and PPP (job description)	
	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;	MVV (Mr. Matěj Hoffmann) is the main contact for communication with NB for approval and implementation of amendments or changes with NB PK01 Quality and Production Manual for Explosive Environments, cap.5.3	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.	MVV communicates with the issuer of the Ex certificate, in terms of the elements of the proposed design changes listed in the certificate and the technical documentation, PK01 Quality and Production Manual for Explosive Environments, cap.5.3	P
	d) the authorization of initial approval and changes to related drawings, where appropriate;	PSK (Mr. Martin Lastuvka) is main contact for communication with NB for approval and realization of appendix or changes. PK01 Quality and Production Manual for Explosive Environments, cap.5.3	P
	e) the authorization of concessions (see 8.7 f));	PSK (Mr. Martin Lastuvka) is main contact for communication with NB for approval and realization of concessions. PK01 Quality and Production Manual for Explosive Environments, cap.5.3	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);	PSK coordinates the assurance of the accuracy of the relevant information regarding the Ex products provided to customers in the	P



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	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.	form of sales literature and installation instructions the procedure for reviewing customer requirements describes PK01 Quality and Production Manual for Explosive Environments, cap.8.2	
	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.	MVV, together with PSK, coordinates production processes related to Ex products, including externally provided products, services and processes described in Chapter 8.4, for which MV is responsible. S04 Production, PK01 Quality and Production Manual for Explosive Environments, cap.8.4	P
	Records demonstrating this shall be available and be maintained as documented information.	PSK coordinates the availability and archiving of records on compliance with the requirements of the production control system for explosive environments, which is set at 10 letters. S01 Documented information management	P
6.1	Actions to address risks and opportunities 6.1 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
6.2	Quality objectives and planning to achieve them 6.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
6.3	Planning of changes 6.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
7.1.1	General (Support and Resources) 7.1.1 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
7.1.2	People 7.1.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
7.1.3	Infrastructure 7.1.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
7.1.4	Environment for the operation of processes 7.1.4 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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	This process is controlled according to S05 Metrological Regulations	P



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	<p>equipment shall be calibrated and a valid calibration certificate shall exist.</p> <p>Verification of measuring equipment against calibrated equipment is also permitted as long as it is properly documented.</p> <p>The calibration certificate shall meet one of the following requirements:</p>	The calibration time periods are defined by the metrologist in the records in an Excel spreadsheet.	
	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.	This process is controlled according to S05 Metrological Regulations	P
	<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:</p> <ul style="list-style-type: none"> · 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. 	This process is controlled according to S05 Metrological Regulations	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	This process is controlled according to S05 Metrological Regulations	P



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	measurement standards by other means (e.g. a documented site assessment).		
7.1.6	Organizational knowledge 7.1.6 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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.	At doublepower, regular training is applied.	P
7.3	Awareness 7.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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 (authorised representatives, importers, distributors, external providers ...), authorities etc.	Internal communication: Competence is defined internally in doublepower. PK01 Quality and Production Manual for Explosive Environments, cap.7.4	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	doublepower has controlled documentation, which is available for staff companys Management review is systematically carried out. S01 Documented information management, S06 Archiving rules	P
7.5.2	Creating and updating 7.5.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P



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Clause	Requirement	Documents reference and/or comments	Verdict
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;	S01 Documented information management, S06 Archiving rules	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;	S01 Documented information management, S06 Archiving rules	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;	S01 Documented information management, PK01 Quality and Production Manual for Explosive Environments, cap.7.5	P
	d) there shall be a documented system that refers all related drawings to the relevant schedule drawings;	S01 Documented information management, records of Ex certificates, registered drawings and procedures	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	S01 Documented information management, PK01 Quality and Production Manual for Explosive Environments, cap.7.5	P
	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.	S01 Documented information management, PK01 Quality and Production Manual for Explosive Environments, cap.7.5	P



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Clause	Requirement	Documents reference and/or comments	Verdict
	<p>g) the manufacturer shall document the body responsible for the verification of the quality management system of each certificate;</p> <p>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.</p>	Certified company and NB are defined.	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;	S01 Documented information management, PK01 Quality and Production Manual for Explosive Environments, cap.7.5, DoJ – quality agreements with suppliers	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;	S01 Documented information management, PK01 Quality and Production Manual for Explosive Environments, cap.7.5, DoJ – quality agreements with suppliers	P
	<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:</p> <ul style="list-style-type: none"> • 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. 	S01 Documented information management, S06 Archiving rules	P
8.1	Operational planning and control 8.1 of ISO 9001:2015 applies with the following addition:		



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	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,4 S04 Prodction	P
8.2.1	Customer Communications 8.2.1 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
8.2.2	Determining the requirements for products and services 8.2.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,2, Review of contract implementation	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, quality management system or marketing documents) that could affect Ex Product compliance.	PSK (Mr. Martin Lastuvka) is main contact for communication with NB for approval and realization of appendix or changes with NB. MVV (Mr. Hoffmann) communicates with the issuer of the Ex certificate, in terms of the elements of the proposed design changes listed in the certificate and the technical documentation, PK01 Quality and Production Manual for Explosive Environments, cap.5.3	P
8.3.1	General (Design and development of products and services) 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		



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	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,2, Review of contract implementation S01 Documented information management	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;	Tests, final inspection and Conformity assessment done in doublepower.	P



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	<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;</p> <p>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:</p> <ul style="list-style-type: none"> – 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, <p>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.</p> <ul style="list-style-type: none"> – a documented site assessment to ensure that all relevant controls are available, documented, understood and effective. <p>NOTE The evaluation takes the following into account:</p> <ul style="list-style-type: none"> – 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. 	<p>PK01 Quality and Production Manual for Explosive Environments, cap.8,4</p>	P
	<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:</p> <ul style="list-style-type: none"> – 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. 	<p>PK01 Quality and Production Manual for Explosive Environments, cap.8,4, Review of contract implementation, Declaration of Conformity Ex external provider</p>	P



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	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;	This process is controlled according to S05 Metrological Regulations	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, Review of contract implementation, Declaration of Conformity Ex external provider	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,4	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.	doublepower follows instructions and requests of NB, DoJ – quality agreements with 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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	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	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers,	P



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Clause	Requirement	Documents reference and/or comments	Verdict
	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;	Declaration of Conformity Ex external provider	
	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	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 the external provider e.g. by a declaration of conformity including test results, if required;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	P
	f) where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch;	Declaration of Conformity Ex external provider	P



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	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, material attestation	P
	<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:</p> <p>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.</p> <p>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.</p> <p>3) Review the material manufacturer's process and data for the validation of material characteristics.</p> <p>4) Confirmation that equipment testing, necessary to confirm the material is in accordance with the</p>	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider, material attestation	P



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	<p>certificate or schedule drawings, is repeated as required.</p> <p>Alternative processes may be utilized if it can be demonstrated that they provide the same level of conformity.</p> <p>Receipt or acceptance of a declaration of conformity does not absolve the manufacturer from responsibility to ensure continuing conformity.</p> <p>NOTE Annex C provides guidance for the development of an external provider's declaration of conformity.</p>		
8.4.3	Information for external providers 8.4.3 of ISO 9001:2015 applies with the following addition:		
	<p>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);</p> <p>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.</p>	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	P
	<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;</p>	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	P
	<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;</p>	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers, Declaration of Conformity Ex external provider	P
	<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.</p>	PK01 Quality and Production Manual for Explosive Environments, cap.8,4, DoJ – quality agreements with suppliers	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:		



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	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,5, OS04 Production	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).	PK01 Quality and Production Manual for Explosive Environments, cap.8,5, OS04 Production WI03 Cap pouring procedure, Output inspection procedure	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,5, OS04 Production	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,5, OS04 Production	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,5, OS04 Production	P
8.5.4	Preservation 8.5.4 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
8.5.5	Post-delivery activities 8.5.5 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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.	PSK (Mr. Martin Lastuvka) is main contact for communication with NB for approval and realization of appendix or changes.	P



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Clause	Requirement	Documents reference and/or comments	Verdict
		PK01 Quality and Production Manual for Explosive Environments, cap.5.3	
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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,6, OS04 Production Output inspection procedure	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,6, OS04 Production Output inspection procedure Operating and maintenance instructions	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,7, OS04 Production WI03 Cap pouring procedure, Output inspection procedure	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,7 a 10.2	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;	PK01 Quality and Production Manual for Explosive Environments, cap.8,7 a 10.2	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	PK01 Quality and Production Manual for Explosive Environments, cap.8,7 a 10.2	P



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Clause	Requirement	Documents reference and/or comments	Verdict
	notice shall be placed in appropriate publications providing recommended action to be taken;		
	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: <ul style="list-style-type: none"> • serial numbers or identification of Ex Products supplied; • the customer who received the Ex Products; • 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; • the action taken to implement corrective and preventative action; 	PK01 Quality and Production Manual for Explosive Environments, cap.8,7 a 10.2	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.	PK01 Quality and Production Manual for Explosive Environments, cap.8,7 a 10.2	P
9.1.1	General (Monitoring, measurement, analysis and evaluation) 9.1.1 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
9.1.2	Customer satisfaction 9.1.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
9.1.3	Analysis and evaluation 9.1.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	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.	PK01 Quality and Production Manual for Explosive Environments, cap.9.2	P
	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,	PK01 Quality and Production Manual for Explosive Environments, cap.9.2	P



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Clause	Requirement	Documents reference and/or comments	Verdict
	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.		
	<p>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.</p> <p>Manufacturers may employ either method or some other equivalent method.</p>	PK01 Quality and Production Manual for Explosive Environments, cap.9.2	P
9.3.1	Management review (General) 9.3.1 of ISO 9001:2015 applies with the following addition:		
	<p>a) the maximum intervals between reviews shall not exceed 14 months;</p> <p>b) top management shall chair the review;</p> <p>c) the Ex authorized person(s) responsible for the activities as detailed in 5.3 shall participate in the review.</p> <p>The review shall include the overall effectiveness of the quality management system with respect to Ex Products, including results of internal and external audits.</p> <p>NOTE Review of results of internal and external audits would provide evidence of the effectiveness of the quality management system.</p>	PK01 Quality and Production Manual for Explosive Environments, cap.9.3	P
9.3.2	Management review inputs 9.3.2 of ISO 9001: 2015 applies.	Manufacturers ISO 9001 QMS complies.	P
9.3.3	Management review outputs 9.3.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
10.1	General (Improvement) 10.1 of ISO 9001:2015 applies.		
	<p>The organization shall retain documented information as evidence of:</p> <p>a) the nature of the nonconformities and any subsequent actions taken;</p> <p>b) the results of any corrective action.</p>	PK01 Quality and Production Manual for Explosive Environments, cap.10	P
10.2	Nonconformity and corrective action 10.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P
10.3	Continual improvement 10.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	P



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Annex A (informative)

Information relevant to particular Types of Protection and specific Ex Products

Clause	Requirement	Documents reference and/or comments	Verdict
A.1	Overview		
	<p>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.</p> <p>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.</p> <p>NOTE The following examples do not cover all Types of Protection but give some advice and will be supplemented in the next edition.</p>		
A.2	General		
	<p>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.</p> <p>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).</p> <p>Statistical bases are not appropriate for routine tests required by the certificate, except where the following currently permit such techniques:</p> <ul style="list-style-type: none"> · the relevant standard; or · appropriate interpretation and clarification sheets; <p>All measurements should consider temperature variations.</p>		
A.3	Ex d – Flameproof enclosures covered by IEC 60079-1		
A.3.1	Verification		
	<p>Verification consists of a visual inspection and/or measurement.</p> <p>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.</p>	<p>PK01 Quality and Production Manual for Explosive Environments, cap.7.1.5, 7.1.5, 7.2</p> <p>S05 Metrological Regulations</p> <p>S02 Human Resources.</p>	P



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Clause	Requirement	Documents reference and/or comments	Verdict
A.3.2	Castings		
	<p>Castings should be subject to verification that demonstrates conformity, e.g.:</p> <p>a) 100 % visual inspection should be done on each part;</p> <p>b) wall thickness (including those parts not subject to machining);</p> <p>c) flaws, inclusions, blow holes and porosity (by either a visual or test method depending upon the criticality).</p> <p>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.</p> <p>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.</p>	Declaration of conformity of supplier, Casting and Inspection Procedures	P
A.3.3	Machining		
	<p>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:</p> <p>a) flatness of flanged flamepaths;</p> <p>b) surface roughness of non-threaded flamepaths;</p> <p>c) fit of all threaded flamepaths (e.g. threaded entries and threaded access covers);</p> <p>d) depth of drilling and tapping of blind holes to ensure adequate residual wall thickness;</p> <p>e) dimensional requirements of all flamepaths.</p> <p>NOTE Suitable statistical techniques are used in ISO 2859-1, ISO 3951-1 or equivalent standard.</p>	Declaration of conformity from supplier, Casting and Inspection Procedures	P
A.3.4	Cemented joints and potted assemblies		
	<p>Documented procedures should address the following, as applicable:</p> <p>a) shelf life and storage of cement, potting compounds;</p>	WI03 Cap pouring procedure	P



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	<p>b) mixing;</p> <p>c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);</p> <p>d) application e.g. filling instructions, freedom from voids and temperature conditions;</p> <p>e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period;</p> <p>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.</p>		
A.3.5	Routine overpressure testing		
A.3.5.1	General		
	<p>The purpose of the test is to check that the enclosure does not suffer damage or permanent deformation.</p> <p>Leakage through cemented joints or potted assemblies would constitute a failure unless otherwise permitted by the issuer of the certificate.</p> <p>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.</p>	N/A	P



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	Due to safety considerations and difficulty in detecting leakage, hydraulic rather than pneumatic methods are recommended.		
A.3.5.2	Batch testing		
	<p>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:</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>d) Batches above 10 000 should be subdivided into smaller batches.</p> <p>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.</p> <p>NOTE Upon non-compliant test results, reconsideration of this batch testing approach is at the discretion of the party issuing the certificate.</p>	N/A	P
A.3.5.3	Welded construction		
	<p>Where permitted by the certificate, the routine overpressure testing may be replaced by one of the following inspection methods:</p> <p>a) radiographic weld inspection; or</p> <p>b) ultrasonic weld inspection; or</p> <p>c) magnetic particle weld inspection; or</p> <p>d) liquid penetrant weld inspection.</p> <p>NOTE ISO standards exist for each of the above weld inspection methods.</p>	N/A	P
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	N/A	P



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	practical, special measure should be taken during the production.		
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.	N/A	P
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.	Drawing and Manufacturing Documentation	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.	Drawing and Manufacturing Documentation Installation Manual	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:	N/A	P



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Clause	Requirement	Documents reference and/or comments	Verdict
	<p>– the air gap (rotor to stator) as specified in the schedule drawings;</p> <p>– the fan clearance as specified in the schedule drawings;</p> <p>– the bearing seal clearances as specified in the schedule drawings.</p> <p>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.</p>		
A.5.4	Windings		
	<p>Documented procedures should ensure that the following are verified:</p> <p>a) wire and insulation system are as specified in the schedule drawings;</p> <p>b) the impregnations process is as specified in the schedule drawings;</p> <p>c) insulation materials are as specified in the schedule drawings;</p> <p>d) mechanical securing of conductors are as specified in the schedule drawings;</p> <p>e) type and mounting of protective devices (e.g. thermal cut-outs) are as specified in the schedule drawings.</p>	Drawing and Manufacturing Documentation	P
A.5.5	Terminal boxes		
	<p>Documented procedures should ensure that the following are verified:</p> <p>a) terminals are as specified in the schedule drawings;</p> <p>b) creepage distances and clearances as specified in the schedule drawings have not been compromised.</p>	Drawing and Manufacturing Documentation	P
A.5.6	Cable Glands, terminals and other accessories		
	<p>The dimensions specified in the schedule drawings should be confirmed on a statistical basis.</p> <p>Where entry openings are secured by non-Ex temporary plugs (e.g. for transport only), additional information should be provided.</p>	Drawing and Manufacturing Documentation	P
A.5.7	Routine verifications and tests		



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Clause	Requirement	Documents reference and/or comments	Verdict
	Procedures for all routine verifications and tests specified in the schedule drawings should be reviewed, along with the results of those verifications and tests.	Design and development management.	P
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.	Declaration of conformity from supplier, Output Inspection Procedure	P
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.	Declaration of conformity from supplier, Output Inspection Procedure	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.	Output Inspection Procedure	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.	Output Inspection Procedure	P



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Clause	Requirement	Documents reference and/or comments	Verdict
A.11.5	Cemented and cast enclosure parts		
	<p>Documented procedures should address the following:</p> <p>a) shelf life and storage of cement, potting compounds;</p> <p>b) mixing;</p> <p>c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);</p> <p>d) application e.g. filling instructions, freedom from voids and temperature conditions;</p> <p>e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period;</p> <p>f) after curing, 100% visual inspection should be done on each assembly.</p>	WI03 Casting Closure Procedure	P
A.11.6	Ingress protection (IP)		
	<p>Documented procedures should ensure that the following is verified:</p> <p>a) weld continuity;</p> <p>b) fitting of gaskets and seals;</p> <p>c) continuity of moulded grooves and tongues;</p> <p>d) application of cements including a visual inspection after curing.</p>	Output Inspection Procedure	P
A.11.7	Routine verifications and tests		
	<p>All tests should be documented. Typical tests include:</p> <p>a) the visual inspection;</p> <p>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.</p>	Output Inspection Procedure, Inspection and Test Records	P
A.12	Ex op – Optical radiation covered by IEC 60079-28		



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Clause	Requirement	Documents reference and/or comments	Verdict
	<p>The following features should be verified for equipment containing source(s) of optical radiation. For components, this normally means verifying the marking on the components or packaging and may be achieved by using statistical techniques where appropriate:</p> <p>a) optical source;</p> <p>b) driver circuit;</p> <p>c) Fibre optic connectors;</p> <p>d) Fibre optic cable;</p> <p>e) enclosure construction;</p> <p>f) optical components, which have an impact on the safety relevant properties of the optical beam (e.g. lenses, filters, mirrors).</p>	<p>Approved components (optical source, driver circuit), Output Inspection Procedure, Inspection and Test Records</p>	P

NOTE: The following pages contain the Certificate list and the Audit non-conformities and observations. These pages are normally created as two separate documents and are attached to the end of the audit report to minimize cut and paste errors.

Depending on the format of the documents added page orientation may need to be changed from portrait to Landscape. In Word 365 and other recent Word versions this may be done in the following manner:

*Select **layout** from the top menu and in the **page setup** pane select the **arrow on the bottom right hand side**. In the new pane select **Orientation**, and either **portrait** or **landscape** and then under **preview** select **this page forward**.*

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4. List of certificates relating to IECEX QAR

IECEX Certificate No.	Description of Ex equipment	Ex marking
Will be added	LED luminaire type SEA EX 1/21	Ex db eb op is IIC T6...T5 Gb Ex tb op is IIIC T85°C Db



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Observations

Additional assessor notes, Summary of audit trail (e.g. Who? What? Where? When? etc.) (Could be positive, negative, improvement, etc). Include brief comments on each department/function audited.

Clause 4

Quality system is certified according to ISO 9001. Expiry date 23.02.2028.
Quality manual + relevant procedures include a requirements of ISO/IEC 80079-34 ed.2
Context + scope of quality system is in conformity with ISO/IEC 80079-34 ed.2.

Clause 5

Quality Policy. The policy is available and documented on company server.
Responsibilities are particularly defined in Quality manual and in PK01 and PPP (job description) (Mr. Hoffmann – Ex representative).

Clause 6

Manufacturers ISO 9001 complies.

Clause 7

Calibration is done by external calibration laboratories with accreditation. All measuring gauges important for type of protections are calibrated.
Internal Ex training has been done 12.12.2024 for relevant personnel.
Internal and external communication are controlled.
Documentation supervision is ensured by information electronics system. Visually difference is done by Ex marking.
Annually verification of standard validity.
Archiving time for Ex documentation is 10 years defined in procedure S01 Documented information management, S06 Archiving rules.

Clause 8

Control (verification) are done in conformity with Annexes A, approved technical documentation (drawings).
Customer communication – communication with customer by checklist about conditions of environment, project approval by Mr. Hoffmann + Mr. Laštůvka.
Ex authorized persons for 8.2.4 and 8.3.6 are identified in PK01 and PPP (job description) (Mr. Hoffmann - development).
Evaluation of important external providers is done once a year (quality, price, term) 12.12.2024.
Contracts with important suppliers for type of protection.
Input control – visual verification of Al castings, sample control of critical diameters, verification of PCBs (electronics).
Company makes at its premises a production, assembly and testing. There is no local assembler.
Production – assembly of components, transition resistance, functional test of luminaires.
Trained people, approved documentation, calibrated gauges, identification and traceability in test protocol, in information electronic system and in delivery note.
Identification (evidence) of product by serial numbers and traceability to customer.
The label includes all necessary data.
To customer is supplied an user manual with all special conditions for use.
Control of nonconforming product – PK01 Quality and Production Manual for Explosive Environments, cap.8,7 a 10.2 includes a commitment to inform the ExCB responsible for quality system and for product certification and customers about supplied unsafe nonconforming product. Evidence of reclamation is sufficient. There is no reclamation on type of protection.

Clause 9

Quality management system is ensured by internal and external audits (ISO 9001 + ATEX).

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Last management review was done on 20.01.2025.

In management review will be evaluated an external audit and reclamations. There is no reclamation on type of protection.

Internal audit with respect to ISO/IEC 80079-34 was done on 12.12.2024.

Clause 10

Manufacturers ISO 9001 complies

Continual improvement is ensured by internal and external audits.

Date: 21.05.2025

Sign: 