QAR No. and customer name	**GB/BAS/QAR07.0040** **5943 - Hansford Sensors Limited**

IECEx QUALITY ASSESSMENT REPORT

INTERNATIONAL ELECTROTECHNICAL COMMISSION

INTERNATIONAL ELECTROTECHNICAL COMMISSION SCHEME FOR CERTIFICATION TO STANDARDS IN EXPLOSIVE ATMOSPHERES (IECEx SCHEME)

TITLE: ATEX/IECEx Quality Assessment Report for Manufacturers.

This document provides an IECEx QAR and ATEX QA Notification Report format for assessment of manufacturers. Guidance for assessment is provided in OD-025 and requirements for preparation of QAR are given in OD-009.

This Document provides a standardised Report format for the recording of assessments of Ex Manufacturers for compliance with the requirements of the following:

ISO/IEC 80079-34 Edition 2.0 2018-08 – Application of Quality Systems for equipment manufacture.

IECEx Operational Document OD 025 – Guidelines for the management of assessment/surveillance of quality management systems in accordance with the IECEx Scheme.

This QAR is applicable to initial assessment, any necessary follow-up assessments, and special assessment of manufacturers.

While primarily intended for use by auditors of certified product manufacturers, it may also be used by manufacturers themselves or when conducting internal assessments for compliance with the relevant requirements.

It is not valid until signed by SGS Baseefa and this is only done when any nonconformities have been cleared. Once completed; in order to be valid for IECEx purposes, this QAR must be registered on the IECEx "On-Line" Certificate of Conformity website system. Refer to OD 011 Part 2 for guidance.

Manufacturer Include Address with post code	**Hansford Sensors Limited** Artisan Hillbottom Road Sands Industrial Estate High Wycombe Buckinghamshire HP12 4HJ
Production Site(s) audited Include Address with post code	As above
Product Description	See attached list of Certificates.
Employee count	Total onsite: 80 Total involved in Ex products: 50
Scope of Audit	Initial Assessment ☐ Re-Assessment ☐ Surveillance Assessment ☒
Electrical equipment with type(s) of protection of	d ☒ i ☒ e ☐ p ☐ m ☐ o ☐ q ☐ n ☐ t ☒ op ☐ h ☐
Ex products as % of overall	20%
Audit Team Leader	David Ford
Audit Date	19 June 2025

Contents:

1. Summary Report

Assessment Summary and Conclusions:

The Hansford Sensors Ltd, High Wycombe facility specialises in the manufacture of accelerometers and monitoring systems.

Since the previous audit Ex Certificates: ExVeritas 24ATEX1830X & IECEx EXV 24.0026X for HS-420d Series Accelerometers have been added to the QAR/QAN Schedule with the addition of the Protection Concept 'Ex d' to the QAR/QAN.

Development of product, assembly, marking, inspection, testing, and calibration activities are undertaken at the Hansford Sensors Ltd, High Wycombe facility. The manufacture of machined components, manufacture and population of printed circuit boards and the supply of electronic components are subcontracted.

The Quality Management System (QMS) is certified to ISO9001:2015. The QMS is effectively maintained through Internal Audits and Management Reviews. The company is also subject to several external third-party audits regarding product approvals.

The QMS is written to meet the requirements of EN ISO/IEC 80079-34:2020 and ATEX Directive 2014/34/EU. The QMS has had some minor changes since the last visit to implement appropriate changes or additions identified in observations from the previous audit.

The products are mature in nature and the understanding within the company of hazardous area products is good. Product controls regarding compliance with Ex Certificates were seen to be generally well planned and implemented including subcontracted items and activities.

Several observations were made which were considered as needing review. These observations were not considered to be non-conformances now but may lead to non-conformities in the future.

The recommendation of the audit is that the QAR/QAN is to be maintained following receipt of satisfactory documentary evidence supporting effective corrective action.

Next Quality Audit due : **01 December 2026**

Next Quality Audit type : **Re-Assessment** ☒
Surveillance ☐

Non-Conformities

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

NCR No.(s): None

Audit Team Leader Recommendations

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

☐ **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/reviewed at next surveillance visit.

☐ **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.

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

☐ **Certification to be refused/suspended*** Close the application/withdraw the notification and inform the Scheme Administrator

Audit Team Leader Signature
Date: 19 June 2025

ExCB Technical Reviewer
Date: 24-07-2025

Certification Body Representative
Date: 24 July 2025

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 : ISO/IEC 80079-34 Edition 2.0 2018-08

List any other reference documents, against which Audit was conducted in addition to IECEx OD 005

2.3 Date(s) and Duration of Audit : 19 June 2025 – 1-day

Include total number of auditor days on site

2.4 Details of ISO 9001 Certification:

ISO 9001 certificate No	Certified by	Expiry date	Scope
10497116	Lloyd's Register Quality Assurance	5 February 2026	Sales, Design, manufacture, repair and calibration of accelerometers and monitoring systems, including intrinsically safe models and provision of associated ancillary equipment.

If ISO 9001 certified, are non-conformities from latest ISO9001 audit reviewed?

Yes ☒ No ☐ N/A (no NCs) ☐

Comments to ISO 9001 non-conformities.

Lloyd's Register Quality Assurance - The last audit date – 28-29 April 2025 – Three Minor NCR's Raised -
1) Clause – 5.1.2 - Customer focus, 2) Clause – 4.4.1 - Quality management system and its processes, &
3) Clause – 8.4.1 - Control of externally provided processes, products and services (General)

2.5 Composition of Audit Team:

Name	Position	Role in Audit *(Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)*
David Ford	SGS UK Ltd. Auditor	Sole Auditor

2.6 Interviewed Representatives of Manufacturer (Auditee):

See Form BAS-F-016 - Meeting Attendance Record (attached)

2.7 Critical Suppliers: (*List critical suppliers reviewed during audit of supplier evaluation)*

Name of Supplier	Critical item or service provided
Electronic Manufacturing Solutions Ltd Fountain House South Horizon West Canal View Road Newbury RG14 5XF	The manufacture and population of printed circuit boards ISO 9001:2015 Certifier: NQA Certification Limited, UKAS 015, Certificate No 172632, Expires 27th March 2027
Euro-Tech (Export) Ltd 518 Purley Way Croydon Surrey CR0 4RE	The supply of electronic components (including critical items) ISO 9001:2015 Certifier: Bureau Veritas Certification, UKAS 0008, Certificate No. UK011562, Version 1, Expires 26th March 2026

2.8 Manufacturers Top Level Documentation: (*List manufactures documentation related to this Quality Audit Report)*

Document No.	Document Name	Rev.	Date
QM01	The Hansford Sensors Limited Quality Manual Overview (QMO)	9	22/07/2024

2.9 Manufacturers IECEx Certificates of Conformity:

See the Schedule to ATEX / UKEX Quality Assurance Notification / IECEx Quality Assessment Report attached

3. Documentation Review and Assessment of Implementation

(For surveillance audits, major document changes only may be reviewed)

NOTE 1: **Manufacturer's Document References** need only to reference the document number (and if desired the title) as the title and revision status is listed in 2.7. **Comments** are 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 9001:2005 the auditor shall provide a verdict in accordance with the Note 3 below.

NOTE 3: Possible audit verdicts: P = Pass, F = Fail, NR = Not Reviewed, NA = Not Applicable, O = Observation and NCR number against a clause means Non-conformity

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.	QMO Section Quality Policy; contains the objective to provide product in compliance with EC Type Certificates and IEC Certificates of Conformity. **Observation a)**	**O**
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.	QMO Section Quality Policy; contains the objective to provide product in compliance with EC Type Certificates and IEC Certificates of Conformity. **Observation a)**	**O**
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**

Clause	Requirement	Documents reference and/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:		
	a) the effective co-ordination of activities with respect to Ex Products;	The Managing Director - Chris Hansford; is the "Authorised Person" for ATEX products. The defined responsibilities are shared with the Finance & Operations Director – Paul Carter, The Technical Director Manager – Ricado Peneda and Quality Manager - Amanda Shepherd. The defined responsibilities are documented in QMO Section – Responsibility and Authority and QF007 - Quality Structure Chart, Issue 030 **Observation b)**	**O**
	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;	QMO Section – Responsibility and Authority	**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.	QMO Section – Responsibility and Authority	**P**
	d) the authorization of initial approval and changes to related drawings, where appropriate;	QMO Section – Responsibility and Authority	**P**
	e) the authorization of concessions (see 8.7 f));	QMO Section – Responsibility and Authority	**P**
	f) the accuracy of relevant information regarding Ex Product given to the customer for any sales	QMO Section – Responsibility and Authority	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.		
	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.	QMO Section – Responsibility and Authority Only one site	**P**
	Records demonstrating this shall be available and be maintained as documented information.	QF007 - Quality structure chart, Issue 030	**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.	The Hansford Sensors Ltd, High Wycombe facility is adequately equipped for the activities undertaken.	**P**
7.1.4	**Environment for the operation of processes** 7.1.4 of ISO 9001:2015 applies.	The work environment is tidy and adequately lit.	**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:	QM16 – Calibration, plant, and equipment control, Issue 4.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.	Accelerometer Bruel & Kjaer 4366 Asset: 111 S/N 897936, Calibration Maintenance & Repair Ltd. UKAS 0645 Certificate No. 1164506 Cal Date 02 July 2024 Due Date 02 July 2025	**P**
	b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information: • an unambiguous identification of the item calibrated; • evidence that the measurements are traceable to international or national measurement standards; • the method of calibration; • a statement of compliance with any relevant specification; • the calibration results; • the uncertainty of measurement, where necessary; • the environmental conditions, where relevant; • the date of calibration; • the signature of the person under whose authority the certificate was issued; • the name and address of the issuing organization and the date of issue of the certificate; • a unique identification of the calibration certificate.	Electrical Safety Tester GW Instek GPT-9804 Asset: 206 S/N GEV160559, Calibration Maintenance & Repair Ltd. Certificate No. 1167349 Cal Date 28 August 2024 Due Date 28 August 2025 Dynamic Signal Analyzer Hewlett Packard 35665A Asset: 85 S/N 3603A03582, Calibration Maintenance & Repair Ltd. Certificate No. 1174429 Cal Date 22 January 2025 Due Date 22 January 2026 Conditioning Amplifier Bruel & Kjaer 2626 Asset: 152 S/N 660093, Calibration Maintenance & Repair Ltd. Certificate No. 1174438 Cal Date 22 January 2025 Due Date 22 January 2026	**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	See Section 7.1.5 b)	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.	QM03 - Training and Competence, Issue 9 and QF87 - Training Matrix, Issue 18, September 2019 was reviewed; The Matrix (Excel Spreadsheet, live document) includes: Production, Admin, Engineering, General Stores, Dispatch, Sales Support Team and Development Tabs. Product specific training documents were available for review.	**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.	QM26 – Communication, Issue 2 and QM04 – Customer Interaction, Issue 5	**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	QM05 – Control of Information, Documents and Records, Issue 6	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	interpretation of quality programs, plans, manuals and records		
7.5.2	**Creating and updating**	Manufacturers ISO 9001 QMS complies.	**P**
	7.5.2 of ISO 9001:2015 applies.		
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;	QM05 – Control of Information, Documents and Records, Issue 6	**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;	QM05 – Control of Information, Documents and Records, Issue 6 and QM23 – Product Variance and Changes, Issue 3	**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;	QM05 – Control of Information, Documents and Records, Issue 6	**P**
	d) there shall be a documented system that refers all related drawings to the relevant schedule drawings;	QM05 – Control of Information, Documents and Records, Issue 6	**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	QM23 – Product Variance and Changes, Issue 3	**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;	QM05 – Control of Information, Documents and Records, Issue 6	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	– 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.		
	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.	Documented in the Schedule to ATEX/UKEX Quality Assurance Notification / IECEx Quality Assessment Report	**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;	QM05 – Control of Information, Documents and Records, Issue 6	**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;	QM05 – Control of Information, Documents and Records, Issue 6 The last annual review of Ex Related Certificates, Standards, regulations, and other external specifications was undertaken on 5th March 2025 (Form QF180)	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.	QM05 – Control of Information, Documents and Records, Issue 6 and QM13 – Production Process, Issue 8	**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.	QMO Section – Quality Management System; documents that the Management System includes the requirements of standard ISO/IEC 80079-34. QM02 – Business Leadership and Reviews, Issue 3, Section – Legislation; documents that the requirements of the ATEX Directive 2014/34/EU are implemented. See Annexes A.2, A.3, A.4 & A.11	**P**
8.2.1	**Customer Communications** 8.2.1 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
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.	QM10 – Sales & Order Processing, Issue 6. The Ex-Product Equipment Group and Protection Concept appear on order acknowledgements. Example Order Acknowledgement HS-100i Series Accelerometer Ref 010/25-26 S/O 75785 07 April 2025 Part Number: HS-100iFLY1005001, Qty 362 for Hanford Sensors, Pune, India, (contains Ex product Marking)	**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.	QM23 – Product Variance and Changes, Issue 3, Section – Design Change Process; requires the Managing Director or Finance & Operations Director to approve any changes to ATEX Related Drawings provided that compliance with the Scheduled Drawings is maintained.	**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**		
	8.3.4 of ISO 9001: 2015 is not within the scope of this document.		

Clause	Requirement	Documents reference and/or comments	Verdict
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.	QM23 – Product Variance and Changes, Issue 3, Section – Design Change Process; requires the Managing Director or Finance & Operations Director to approve any changes to ATEX Related Drawings provided that compliance with the Scheduled Drawings is maintained.	**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;	QM11 – Purchasing, Issue 5 The responsibility for ensuring conformance with the certificate and the technical documentation is not sub-contracted	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.	QM11 – Purchasing, Issue 5 ISO 9001 Certification and Visit reports are maintained See Section 2.7 - Critical Suppliers	**P**
	2) where the features affecting the Type of Protection cannot be verified at a later stage or are not verified by the manufacturer e.g. encapsulated intrinsically safe circuits, then the product, process, or service shall only be accepted by one of the following methods: – the manufacturer can demonstrate that the control process implemented by the external providers ensures Ex compliance, – the body responsible for the verification of the quality management system performs periodic audits at the external providers.	QM11 – Purchasing, Issue 5 No components are supplied by external suppliers that contain special processes	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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;	QM11 – Purchasing, Issue 5 Example: Calibration Maintenance & Repair Ltd, Unit 11, Frensham Road Norwich, Norfolk NR3 2BT UKAS Accredited Calibration Laboratory 0654	**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;	QM11 – Purchasing, Issue 5	**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;	See 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.	QM11 – Purchasing, Issue 5	**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.	A requirement in contract terms and conditions	**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;	QM11 – Purchasing, Issue 5 QM12 – Stock Control and Kitting, Issue 5.	**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,	QM11 – Purchasing, Issue 5 QM12 – Stock Control and Kitting, Issue 5.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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;		
	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;	QM11 – Purchasing, Issue 5 QM12 – Stock Control and Kitting, Issue 5.	**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;	No routine testing is undertaken by suppliers	**N/A**
	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;	No Special Processes were identified	**N/A**

Clause	Requirement	Documents reference and/or comments	Verdict
	f) where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch;	QM11 – Purchasing, Issue 5 QM12 – Stock Control and Kitting, Issue 5.	**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;	Currently no requirement for training or specialist skill or knowledge	**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;	Applicable routine testing is undertaken by the manufacturer	**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;	Ex certificates are available as required	**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;	QM11 – Purchasing, Issue 5 QM12 – Stock Control and Kitting, Issue 5.	**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.	QM11 – Purchasing, Issue 5 QM12 – Stock Control and Kitting, Issue 5.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.		
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.	QM11 – Purchasing, Issue 5	**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;	No special processes were identified	**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;	QM11 – Purchasing, Issue 5	**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.	See 8.4.3 c)	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
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.	QM13 – Production Process, Issue 8. Assembly procedure (Build Sheet) IMI Series (Intrinsically Safe Inner Module Series) Assembly Instructions for HS-100i, Revision B HS-100i Series Accelerometer Part Number: HS-100iFLY1005001, W/O No. 173310, Qty 362 for Hanford Sensors, Pune, India, was the subject of audit	**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).	Potting and Welding documented in assembly procedure (Build Sheet) IMI Series (Intrinsically Safe Inner Module Series) Assembly Instructions for HS-100i, Revision B	**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;	QM13 – Production Process, Issue 8 & QM24 - Branding Products, Issue 3 Ex Product HS-100 Series Accelerometer manufactured to Ex Certificates: Baseefa07ATEX0144X IECEx BAS 07.0035X was found to be in conformance with marking drawing M06-001-D, General Arrangement and Product Information for Group I, Group II and Group III Accelerometer, Issue D Stencel Using: A04-004	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.	QM13 – Production Process, Issue 8 & QM24 - Branding Products, Issue 3	**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 customer supplied property is incorporated into Ex product	**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.	QM23 – Product Variance and Changes, Issue 3, Section – Design Change Process; requires the Managing Director or Finance & Operations Director to approve any changes to ATEX Related Drawings provided that compliance with the Scheduled Drawings is maintained.	**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.	QM13 – Production Process, Issue 8. Routine 500V HIPOT Dielectric Strength/Isolation Testing is undertaken.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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.	QM13 – Production Process, Issue 8. Product Data Sheet - HS-100i Intrinsically Safe Accelerometer, TS035.22 (Contains Special conditions of safe use) QF042-001 - EU Declaration of Conformity for Baseefa07ATEX0144X, (QF042-001, Issue 3) **Observation c)** **Observation d)**	**O**
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;	QM25 – Product Recall, Issue 4.	**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;	QM25 – Product Recall, Issue 4.	**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;	QM25 – Product Recall, Issue 4.	**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;	QM25 – Product Recall, Issue 4.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	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: • 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;	QM25 – Product Recall, Issue 4.	**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.	QM15 - Complaints and NCRs, Issue 8 Section Responsibility - No concessions are acceptable on Ex product	**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.	QM15 - Complaints and NCRs, Issue 8 No safety related customer complaints have been received. A Customer satisfaction "Survey Monkey" Survey was undertaken in July 2023.	**P**
9.1.3	**Analysis and evaluation** 9.1.3 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
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.	QM08 - Internal Audits, Issue 3.	**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, 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.	The last (*vertical*) internal audit A15-25 dated 06 January 2025 covered Ex product (HS420i 0255012).	**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. Manufacturers may employ either method or some other equivalent method.	See Section 9.2 b)	**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.	QM02 – Business Leadership and Reviews, Issue 3 The last Management Review A01-24 was undertaken on 7th August 2024, the correct management personnel were present, and the review included the effectiveness of the quality management system with respect to Ex products.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
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.		
	The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action.	QM15 - Complaints and NCRs, Issue 8 QM08 - Internal Audits, Issue 3. QM09 – Actions, Revision 4 QM02 – Business Leadership and Reviews, Issue 3	**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**

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.

Clause	Requirement	Documents reference and/or comments	Verdict
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.		P
	Comments		
	Certificates of Conformity and Material Inspection Certificates are available: Example: M05-052 – IS 19mm Isolation Can Top Exit, Issue B – Material: 303 Stainless Steel Leaside Turned Parts Ltd,, Delivery Note/C of C 012378, Cust Order PO26296, M05-052 – IS 19mm Isolation Can Top Exit, Issue B, Qty 200, 02/06/2025. (Material: 303-S-31)		

A.3	**Ex d – Flameproof enclosures covered by IEC 60079-1**		
A.3.1	**Verification**		
	Verification consists of a visual inspection and/or measurement. The measurement should be done with suitable measuring equipment. The persons doing this measurement should have the competence and knowledge of using this measuring equipment.	HS-420d Series Accelerometers ExVeritas 24ATEX1830X IECEx EXV 24.0026X QM11 – Purchasing, Issue 5 QM12 – Stock Control and Kitting, Issue 5. QM16 – Calibration, plant, and equipment control, Issue 4.	**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.	The Ex-product assembly includes a pre certified Casting: Range of conduit fittings CML 16ATEX1325X IECEx QPS 16.0012X CML 22UKEX1751X Protection concepts Ex db and Ex tb	**P**
A.3.3	**Machining**		
	Machining should be subject to verification by either 100 % inspection or statistical techniques as appropriate that demonstrates conformity, e.g. the following should be verified: a) flatness of flanged flamepaths; b) surface roughness of non-threaded flamepaths; c) fit of all threaded flamepaths (e.g. threaded entries and threaded access covers); d) depth of drilling and tapping of blind holes to ensure adequate residual wall thickness; e) dimensional requirements of all flamepaths. NOTE Suitable statistical techniques are used in ISO 2859-1, ISO 3951-1 or equivalent standard.	M02-156-B - Ex d Sensor Base M8 Female, Revision B At present only prototype samples have been produced. When vendor is selected purchase orders will ask for dimensional verification, a declaration of conformity and material certification	**P**

A.3.4	**Cemented joints and potted assemblies**		
	Documented procedures should address the following, as applicable: a) shelf life and storage of cement, potting compounds; b) mixing; c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion); d) application e.g. filling instructions, freedom from voids and temperature conditions; e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period; f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process and the potted assembly, this could be for example using statistical techniques.	AI093 - HS-420d Series Assembly instructions, Issue A Application of Loctite 272 thread lock (AL009) to the reducer adapter M01- and sensor base Place in the oven for 30 minutes at 90 deg C	**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.	Test Report R5089/A/1 GB/EXV/ExTR24.0043/00 Section IEC 60079-0, Clause 27 - Routine tests - No routine tests required	**N/A**

A.3.5.2	**Batch testing**		
	Where permitted by the certificate, the routine overpressure testing may be replaced by a batch test according to the following criteria, based on ISO 2859-1: a) For a production batch up to 100, a sampling of 8 should be tested at 1,5 times the reference pressure with no failures. b) For a production batch from 101 to 1 000, a sampling of 32 should be tested at 1,5 times the reference pressure with no failures. c) For a production batch from 1 001 up to 10 000, a sampling of 80 should be tested at 1,5 times the reference pressure with no failures. d) Batches above 10 000 should be subdivided into smaller batches. If there are any non-compliant test results,100 % of all remaining samples in the batch should be tested at 1,5 times the reference pressure. Future batches should be routine tested at 1,5 times the reference pressure until confidence is established to reconsider batch testing. NOTE Upon non-compliant test results, reconsideration of this batch testing approach is at the discretion of the party issuing the certificate.	Test Report R5089/A/1 GB/EXV/ExTR24.0043/00 Section IEC 60079-0, Clause 27 - Routine tests - No routine tests required	**N/A**
A.3.5.3	**Welded construction**		
	Where permitted by the certificate, the routine overpressure testing may be replaced by one of the following inspection methods: a) radiographic weld inspection; or b) ultrasonic weld inspection; or c) magnetic particle weld inspection; or d) liquid penetrant weld inspection. NOTE ISO standards exist for each of the above weld inspection methods.	Not a welded construction	**N/A**
A.3.6	**Flanged joints**		
	Flanged joints should be verified after final assembly to ensure the gap specified in the Schedule Drawings is not exceeded. If not practical, special measure should be taken during the production.	No flanged joints in Ex db product audited	**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 sintered components in Ex db Product audited	**N/A**

A.4	**Ex i – intrinsic safety covered by IEC 60079-11**		
A.4.1	**Components for intrinsically safe products**		
	The following features should be verified with respect to the following components for use in intrinsically safe apparatus and associated apparatus. This normally means verifying the marking on the components or packaging and may be achieved by using statistical techniques where appropriate, as shown in Table A.1:	HS-100 Series Accelerometer Baseefa07ATEX0144X IECEx BAS 07.0035X QM12 – Stock Control and Kitting, Issue 5 – Additional Intrinsically Safe requirements (IEC 80079-34) Safety Device = R3 – Fitted as 0603 1% 56kΩ 1/10W 100PPM PCB Conforms to UL Approval P02-003 – HS-100I PCB Component Layout, Revision C Ex-Product contains Resistors, Diodes and Piezoelectric Crystal	**P**
Table	**Table A.1 Component features requiring compatibility**		
	Resistors:	value, power, type, tolerance, case size	**P**
	Capacitors:	value, tolerance, type, rated voltage, case size	**P**
	Piezo-electric devices:	manufacturer, type, capacitance	**P**
	Inductive components:	type, inductance, DC. resistance, number of turns, wire gauge and material, material specification of core and bobbin where appropriate	**N/A**
	Transformers:	type, manufacturer, isolation, voltage	**N/A**
	Optical isolator	Optical isolator type, isolation, voltage”	**N/A**
	Semiconductors: – Diodes – Zener diodes – Transistors – Integrated circuits – Thyristors	type number, power value and where appropriate, the manufacturer	**P**
	Cells and batteries:	manufacturer and type number, or IEC designation	**N/A**
	Fuses:	manufacturer, type, value	**N/A**
	Insulating materials:	specification, dimensions and where appropriate type number	**P**
	Connectors (e.g. plugs/ sockets and terminals):	type number and where appropriate, the manufacturer	**N/A**

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.	Electronic Manufacturing Solutions Ltd Certificate of Conformance/Release Note: 00016471, Qty 600, P02-003 – 100 Series AC PCA-Blue PCB, Issue B PCB Conforms to UL Approval 13mm Dia, 0.8mm thick 1oz Copper clad epoxy Glass laminate (FR4) CTI >175 Data provided on drawings and Gerber files	**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.	Documented in Assembly procedure (Build Sheet) IMI Series (Intrinsically Safe Inner Module Series) Assembly Instructions for HS-100i, Revision B Note 12 - Conformal Coating Electronic Manufacturing Solutions Ltd Certificate of Conformance/Release Note: 00016471, Qty 600, P02-003 – 100 Series AC PCA-Blue PCB, Issue B Safety Device = R3 – Fitted as 0603 1% 56kΩ 1/10W 100PPM PCB Conforms to UL Approval	**P**

	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, insulation thickness are in conformity with the schedule drawings.		
A.4.3	**Sub-assemblies and assemblies**		
	Documented procedures should ensure that production documentation includes all relevant variations to the product design. Production documentation should address all safety critical components, and in the case of encapsulated parts, the compound manufacturer, type, mix and minimum depth. Documented procedures should address the following: a) shelf life and storage of cement and potting compounds; b) mixing; c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion); d) application e.g. filling instructions, freedom from voids and temperature conditions; e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period; f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process and the	QM13 – Production Process, Issue 78 Assembly procedure (Build Sheet) IMI Series (Intrinsically Safe Inner Module Series) Assembly Instructions for HS-100i, Revision B Note 5 - Potting Sheet AI002 – Mixing details for standard potting, 12/09/14 Stycast 2057 Batch No. 0251022174, Use By 26/02/2026 Cure in oven @ 90°C for 1 Hour Note 16 - Welding IP68	**P**

	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: d) the gaskets correspond to the quoted specification; e) 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.	The enclosure is a fully welded construction	**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	Assembly procedure (Build Sheet) IMI Series (Intrinsically Safe Inner Module Series) Assembly Instructions for HS-100i, Revision B Test - 500V Isolation Test	**P**

	conducted on a 100 % basis unless otherwise permitted.	TI001 – Test Instruction (Inner module) HS-100i HS-100T & HS-100i, HS-100M & HS-100A Series, Revision F QF040 – Work in Progress Result Form, Issue16 500V rms HIPOT Dielectric Strength/Isolation Testing for 1 Minute Test Report GB/BAS/ExTR07.0076/00, Section 6.1	
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.	Intrinsically safe circuits and assemblies are not incorporated in Ex equipment of other types of protection	**N/A**

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.	HS-420 Series Accelerometer Baseefa08ATEX0086X IECEx BAS 08.0034X (Ex tD) No castings in Ex tD product	**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.	QM12 – Stock Control and Kitting, Issue 5 – Additional Intrinsically Safe requirements (IEC 80079-34) The enclosure is a fully welded construction	**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.	No gaskets in Ex tD product The enclosure is a fully welded construction	**N/A**
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 in Ex tD product	**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;	No Cemented and cast enclosure parts in Ex tD product	**N/A**

	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.		
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.	Assembly procedure (Build Sheet) A1030 – HS-420 & HS-422 Intrinsically Safe Series Assembly Instructions, Revision H WI007 – HS-420 Series Welding Instruction – Cable Versions, Revision B Pages 9 and 10 QF048 – Work in Progress Result Form, Issue 11 IP65	**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.	Assembly procedure (Build Sheet) A1030 – HS-420 & HS-422 Intrinsically Safe Series Assembly Instructions, Revision H QF048 – Work in Progress Result Form, Issue 11	**P**

4. Observations

Observation a): Review both the "Stand Alone" Quality Policy and the Quality Policy in the Quality Manual should be reviewed to ensure that they include the objective that the "*Ex-product conforms to the type described in the Ex-certificate and the technical documentation*".

Observation b): The appointment of the "Authorised Person" and the defined responsibilities of standard ISO/IEC 80079-34 Clause 5.3 a) to g) are documented in QMO Section – Responsibility and Authority and QF007 - Quality Structure Chart, Issue 030. It would be helpful to clarify the delegation/sharing of the defined responsibilities with the appropriate personnel.

Observation c): On review of to the EU Declaration of Conformity for Ex Certificate Baseefa07ATEX0144X (*QF042-001, Issue 3*); reference to SGS Baseefa as a notified body should be removed
See ATEX 2014/34/EU Guidelines, 5th Edition – April 2024, Section 227 – The EU Declaration of Conformity (Page 194).

Observation d): The harmonisation status of standard EN 60079-0:2012 + AII:2013 detailed on the EU Declaration of Conformity for Ex Certificate Baseefa07ATEX0144X (*QF042-001, Issue 3*); expired in July 2021.

Document History:

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