IECEx/ATEX QUALITY ASSESSMENT REPORT

Report No.:	**TRA-060443-32-00A**	**QAR No.:**	**GB/TRC/QAR15.0002/05**
CTS Ref. No.:	**GU-ZETQ-0002**	**QAN No.:**	**TRAC13QAN0011 R11**
		UKQAN No.:	**N/A**

Project No.	GU-ZETQ-0002		
Ex QMS Certificates	-		
Manufacturer Include Address with post code	Zettlex (UK) Ltd. Newton Court, Town Street, Newton, Cambridge. CB22 7PE. United Kingdom.		
Production Site(s) audited Include Address with post code	Zettlex (UK) Ltd. Newton Court, Town Street, Newton, Cambridge. CB22 7PE. United Kingdom		
Product Description	Programmable Encoder type ST-4312-V2-A		
Employee count	Total onsite: 45	Total involved in Ex products: 5	
Scope of Audit	Initial Assessment ☐ Re-Assessment ☐	Surveillance Assessment ☒ Special Assessment ☐	
Scheme	IECEx ☒	ATEX ☒	UKEX ☐
Ex equipment with type(s) of protection	d ☐ e ☐ i ☒ m ☐ nA ☐ nC ☐ nR ☐ o ☐ p ☐ q ☐ t ☐ op ☐ h ☐ c ☐ b ☐ k ☐ Flame arrestors ☐ Other *(specify)* ☐		
Audit Team Leader	Damian Broadley		
Audit Date	2022-12-13		

Throughout this report the date format yyyy-mm-dd is used. This report may only be reproduced in its entirety and without change.

Contents:

IECEx ExCB / Auditing body

Element Materials Technology
Unit 1, Pendle Place, Pimbo Industrial Estate,
Skelmersdale, West Lancashire, WN8 9PN,
United Kingdom

1. Summary Report

Assessment Summary and Conclusions:

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

The objective of this audit was to establish that the Production Site audited complies with the rules of the IECEx System, the ATEX Directive (for Element Rotterdam BV, Notified Body 2812), as they apply to the manufacture of equipment for use in potentially explosive atmospheres.

The quality system effectively controls production in accordance with the certification documents, and thus supports the manufacture of Ex equipment.

During this audit the effectiveness of the corrective actions regarding previously identified nonconformities was checked.

This audit is based on a sampling process based on the available and hence not all aspects the quality system may have been addressed.

There were no deviations from the audit plan nor any significant issues impacting the audit program.

At the next audit, the verification of equipment and associated documentation should include examples of equipment from certificates other than those checked at this audit so that the full range of certified equipment is reviewed over the full audit cycle. See section 4 of this report for the full list of applicable certificates and identification of those certificates that were reviewed at this audit.

The objectives of the audit were considered to be fulfilled.

Next Quality Audit due : 2024-07-08 (Re-assessment due)

Non-Conformities (refer to section 5)

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

NCR No.(s): NCR01

Audit Team Leader Recommendations

☒ **Notification / Certification to be maintained** following receipt of satisfactory documentary evidence supporting effective corrective action. Corrective action to be verified at next surveillance visit

Audit Team Leader Signature
2022-12-13

ExCB Reviewer Signature
2023-01-19

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 in section 2.4*

2.2 Audit Criteria

List any other reference documents, against which Audit was conducted

:

EN ISO/IEC 80079-34:2020 with ISO 9001:2015 ☒

ATEX 2014/34/EU Annex IV ☒

UKEX SI 2016:1107 Schedule 3A, Part 2 5 ☐

ATEX Guidelines 2020 ☒

2.3 Date(s) and Duration of Audit

Include total number of auditor days on site

: 2022-12-13, 1 day

2.4 Certified Quality System:

ISO 9001 Certificate No	Certified by	Expiry date	Scope
DAS17989364/0/Q Rev3	DAS	2024-10-25	Design and manufacture of Electronic sensors and associated services.

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 COMMENTS NO NCR'S

2.5 Composition of Audit Team:

Name	Position	Role in Audit *(Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)*
Damian Broadley	Factory audit team leader	Sole auditor

2.6 Interviewed Representatives of Manufacturer (Auditee):

Name	Position	Open	Close
John Parsons	Operations Manager	☒	☒
		☐	☐
		☐	☐
		☐	☐

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
Circuit Solutions	PCB

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)*

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Ev.	NC	Document No.	Document Name	Rev.	Date
Ev1	☐	DAS17989364/0/Q	ISO 9001 certificate	3	2024-10-25
Ev2	☐	QM-001	Quality Manual	5.6	2022-08-11
Ev3	☐	AP-500	Management Responsibility (checked not collected)	3.4	2020-01-22
Ev4	☐	SP-720	Procedure for Customer related Process	8.0	2019-11-21
Ev5	☐	AP-423	Document Control	4	2021-11-03
Ev6	☐	-	Interested parties Registers	-	-
Ev7	☐	AP-424	Control of Records	1.4	2019-07-04
Ev8	☐	AP-740	Purchasing Procedure	3.4	-
Ev9	☐	QP-830	Non – Conforming Procedure	1.4	-
Ev10	☐	-	Training Matrix (checked not collected)	--	-
Ev11	☐	WO19312	WORKS ORDER	-	-
Ev12	☐	PO-40356	PURCHASE ORDER 30003106		
Ev13	☐	PO-40356	Delivery note 22100008	-	2020-11-07
Ev14	☐	1011-533	Potting procedure	1-1	-
Ev15	☐	-	Programmable Encoder EU DOC	-	-
EV16	☐	ZEN030	WRIST STRAP		2022-01-13
Ev17	☐	4312-101	Label drawing (checked not collected)	1	-
Ev18	☐	-	Label(checked not collected)	-	-

Ev.	NC	Document No.	Document Name	Rev.	Date

- *A code "(NE)" suffix in the "Document Name" column indicates that the documentation was not in the English language. The auditor has confirmed that they have the necessary language skills to read and understand this document.*
- *A check in the box in the "NC" column indicates that the document was checked but not collected at this audit.*

2.9 Audit report history:

Revision	Description	Issue date
A	Original audit report	2022-12-14

3. Documentation Review and Assessment of Implementation

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

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

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

Clause	Requirement	Documents or Comments	Verdict
4.1	**Understanding the organization and its context** 4.1 of ISO 9001:2015 applies with the following addition:		
In regard to this document, the context of the organization is to ensure that any Ex Product is in accordance with its certificate and technical documentation.		The manufacturer maintains an ISO 9001 Quality Management system (QMS) (Ev1) with additional detail to support ISO 80079-34. The Quality Manual is known as QM-001 (Ev2).	**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.		There is a Quality Manual that complies with ISO IEC 80079-34 (Ev2)	**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;		Page 2, Section 2.8 of document AP-500 (EV3) details the authorized person.	**P**
b) the liaison with the issuer of the certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the certificate and the technical documentation;		Page 2, Section 2.8 of document AP-500 (EV3) details the authorized person..	**P**

Clause	Requirement	Documents or Comments	Verdict
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.		Page 2, Section 2.8 of document AP-500 (EV3) details the authorized person.	**P**
d) the authorization of initial approval and changes to related drawings, where appropriate;		Page 2, Section 2.8 of document AP-500 (EV3) details the authorized person..	**P**
e) the authorization of concessions (see 8.7 f));		Concessions are not permitted.	**N/A**
f) the accuracy of relevant information regarding Ex Product given to the customer for any sales literature and installation instructions (which shall include applicable Specific Conditions of Use and any Schedule of Limitations); NOTE: Ex Equipment Certificate numbers with a suffix "X" contain Specific Conditions of Use. Ex Component certificates numbers, with a suffix "U" may contain a Schedule of Limitations.		Page 2, Section 2.8 of document AP-500 (EV3) details the authorized person.	**P**
g) the effective coordination of manufacturing processes related to Ex Products including externally provided products, services and processes detailed in 8.4; In the case of a manufacturer with multiple manufacturing sites an Ex authorized person with relevant responsibilities shall be appointed for each site.		Page 2, Section 2.8 of document AP-500 (EV3) details the authorized person.	**P**
Records demonstrating this shall be available and be maintained as documented information.			**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 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.		Spreadsheet defines the calibration process required by ISO 9001.	**P**

Clause	Requirement	Documents or Comments	Verdict
The calibration certificate shall meet one of the following requirements:		Examples of calibration records for a ZEN030 were collected (Ev16).	
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.			**N/A**
b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information: • an unambiguous identification of the item calibrated; • evidence that the measurements are traceable to international or national measurement standards; • the method of calibration; • a statement of compliance with any relevant specification; • the calibration results; • the uncertainty of measurement, where necessary; • the environmental conditions, where relevant; • the date of calibration; • the signature of the person under whose authority the certificate was issued; • the name and address of the issuing organization and the date of issue of the certificate; • a unique identification of the calibration certificate.		Calibration is not carried out by an accredited calibration laboratory, but the certificates contain the minimum required information. Example certificates (EV16).	**P**
c) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority or does not contain the information listed in 7.1.5 b), the manufacturer shall demonstrate a valid relationship to international or national measurement standards by other means (e.g. a documented site assessment).			**N/A**
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.		Training Matrix used, full training appears to be given (EV10)	**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.		Quality Manual reviewed during the audit covers this requirement. (Ev2)	**p**

Clause	Requirement	Documents or Comments	Verdict
NOTE 2: External communication includes communication with clients, certification bodies, providers, economic operators (authorized representatives, importers, distributors, external providers...), authorities etc.			
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		The quality management system documentation provides a consistent interpretation of quality programs, plans, manuals and records (Ev2)	**P**
7.5.2	**Creating and updating** 7.5.2 of ISO 9001:2015 applies.	Manufacturers ISO 9001 QMS complies.	**p**
7.5.3	**Control of documented Information** 7.5.3 of ISO 9001:2015 applies with the following addition:		
a) technical documentation and manufacturer's documentation shall be controlled;		Procedure for Customer related processes (EV4) defines the control of documentation and works in conjunction with AP-423 Document Control (Ev5).	**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;		Procedure Customer related processes (EV4) ensures that information contained within manufacturer's documentation is compatible with the technical documentation.	**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;		Procedure Customer related processes (EV4) defines the control of items covered by scheduled drawings. The Ex marking on the equipment was checked and confirmed against drawing 4312-101 rev1.0 (Ev17). A copy of the label applied was obtained (Ev18).	**p**
d) there shall be a documented system that refers all related drawings to the relevant schedule drawings;		Procedure for Customer related processes (EV4) defines the control of documentation.	**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		Procedure for Customer related processes (EV4) defines the control of documentation.	**P**

Clause	Requirement	Documents or Comments	Verdict
	that the change to the component for the one product is not implemented without approval from the responsible persons for all end-products that use that component.		
	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.	Procedure for Customer related processes (EV4) defines the control of documentation.	**P**
	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.	Document Interested parties Registers (EV6) specifies the body responsible for the verification of the quality management system of each certificate.	**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;	Procedure for Customer related processes (EV4) defines the control of documentation passed to 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;	A copy of the EU DoC for Programmable Encoder (EV15) was checked for validity against the relevant standards lists.	**NCR1**
	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.	Procedure AP-424 (EV7) defines the controls required by ISO 9001.	**P**
8.1	**Operational planning and control** 8.1 of ISO 9001:2015 applies with the following addition:		

Clause	Requirement	Documents or Comments	Verdict
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.		See Annex A of this report for further details.	**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.		The product is designed and sold to two customers only, both are familiar with certification parameters. Contact reviews are currently conducted via email	**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.		See clause 5.3 for person responsible for the approval process.	**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.		
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.		See clause 5.3 for person responsible for the approval process.	**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;			**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;		Procedure AP-740 (Ev8) details how external providers are selected.	**P**

Clause	Requirement	Documents or Comments	Verdict
	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.		
	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.		**N/A**
	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;		**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;	Procedure AP-740 (Ev8) details how external providers are re-evaluated.	**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;		**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.	Procedure AP-740 (Ev8) details how external providers are re-evaluated.	**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.		**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	Procedure AP-740 (Ev8) details the verification arrangements employed.	**P**

Clause	Requirement	Documents or Comments	Verdict
	demonstrate the product's compliance with the certificate, considering the nature of the product and the nature of the external provider;		
	b) when deciding what type of verification is required for a particular purchased process, product or service, the manufacturer shall consider the nature of the purchased product, the external provider, and how critical it is to the Type of Protection. In considering whether the external provider should carry out the verification, the manufacturer should consider the results of their evaluation carried out under 8.4.1. The decision should reflect the competence of the external provider, including whether they have a quality management system that covers the activity, the resources, e.g. equipment, and the people with sufficient skill and experience to do it. This latter point is particularly significant when judgement is required, such as when inspecting a flameproof casting. When the manufacturer elects to have the external provider carry out test or inspection that is relevant to the Type of protection, the product may be supplied with a declaration of conformity that confirms it has been done;	"Goods inwards" procedure AP-740 (Ev8) details how the external provider proves evidence of conformity.	**P**
	c) where the external provider has been evaluated and documented objective evidence has been obtained to demonstrate that the external provider is fully capable of producing and verifying the process, product or service, no further verification of the process, product or service is required, if a declaration of conformity is supplied for each batch or product;		**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;	Routine tests or inspections were not required.	**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;	The supplier declaration of conformity (EV13) refers to purchasing documents, quality plan or procedure.	**p**
	f) where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch;		N/A
	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;		N/A
	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;		N/A
	i) where an external provider provides product with evidence of conformity applicable to use in an explosive atmosphere, (e.g. certificate), then further verification is not required unless the manufacturer considers it necessary;		N/A

Clause	Requirement	Documents or Comments	Verdict
	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;		N/A
	k) One of the following processes shall be used to verify the continued conformity of the materials critical to the applied Type of Protection, used in the production of the Ex Products: 1) Review the Declaration(s) of Conformity from the external provider of the material within the supply chain that can impact the material characteristics; as applicable; to demonstrate that the material used in the production of the Ex product is in accordance with the schedule drawings. 2) Review the material manufacturer's confirmation that the material maintains the particular material properties of concern; e.g. flammability, CTI, RTI, or UV resistance, chemical composition, physical properties. 3) Review the material manufacturer's process and data for the validation of material characteristics. 4) Confirmation that equipment testing, necessary to confirm the material is in accordance with the certificate or schedule drawings, is repeated as required Alternative processes may be utilized if it can be demonstrated that they provide the same level of conformity. Receipt or acceptance of a declaration of conformity does not absolve the manufacturer from responsibility to ensure continuing conformity. NOTE: Annex C provides guidance for the development of an external provider's declaration of conformity.	The process k1 was used to verify the continued conformity of critical materials.	**p**
8.4.3	**Information for external providers** 8.4.3 of ISO 9001:2015 applies with the following addition:		
	a) the purchasing documents shall clearly describe the specific requirements pertaining to externally provided product set out in the certificate and the technical documentations (e.g. for process control, testing or inspection); NOTE: For particular types of product e.g. castings, machined items and assemblies, the purchasing documents commonly include specific references to required drawings, test procedures, inspection procedures, material certificates, test reports and Declarations of Conformity.	The manufacturer had purchasing Procedure AP-740 (Ev8)) that describes how requirements are relayed to suppliers. An example of purchasing information passed to a supplier is 30003106 (EV12).	**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;		**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;	The manufacturer had purchasing Procedure AP-740 (Ev8) that describe how traceability is maintained.	**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.		**N/A**
8.5.1	**Production and service provision (Control of production and service provision)** 8.5.1 of ISO 9001:2015 applies with the following addition:		
	The manufacturer shall provide procedures, production equipment, working environments and inspection/testing facilities that together	The manufacturer provided procedures (WO19312),	**P**

Clause	Requirement	Documents or Comments	Verdict
provide assurance with respect to the compliance of the Ex Product with its technical documentation.		production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the product with the type as described in the Ex certificate. EV11 refers.	
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).			**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;		Batch numbers used for traceability.	**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.		WO19312 Ev11	**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.			**N/A**
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.			**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.			**N/A**
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.		A copy of the instructions for was reviewed and confirmed against the certificate.	**p**
8.7	**Control of nonconforming outputs** 8.7 of ISO 9001:2015 applies and the following shall be defined:		

Clause	Requirement	Documents or Comments	Verdict
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;		Procedure QP-830 (EV9) addressed control of non-conforming product and contained all items (a) to (f), including the implementation of the recommendations in the NOTES.	**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;		The product recall process ensures that there is a means for keeping the ExCB or approved/notified bodies fully informed.	**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;			**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;			**P**
e) for all nonconforming Ex Products that have been supplied to a customer, the manufacturer shall maintain, for a minimum period of 10 years, records of: 1) serial numbers or identification of Ex Products supplied; 2) the customer who received the Ex Products; 3) the action taken to inform customers and the body responsible for the verification of the quality management system in the case of unsafe nonconforming Ex Products; 4) the action taken to implement corrective and preventative action;			**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.			**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.			**NCR01**
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,			**NCR01**

Clause	Requirement	Documents or Comments	Verdict
storage, training of staff and any other elements of the system which can affect the compliance of the Ex Product to the certification parameters.			
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.			**NCR01**
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.		The management review is conducted weekly at a management level and a full quality meeting quarterly. Reviewed during the audit.	**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)**		**p**
	10.1 of ISO 9001:2015 applies.		
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.	
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.

A.3 – A.13	**Information relevant to Electrical Equipment**	P

Clause	Requirement	Documents or Comments	Verdict
A.3	**Ex d – Flameproof enclosures covered by IEC 60079-1**		**N/A**

Clause	Requirement	Documents or Comments	Verdict
A.4	**Ex i – intrinsic safety covered by IEC 60079-11**		

A.4.1	**Components for intrinsically safe products**		
	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:	The manufacturer had a procedure for verifying the parameters of the critical components listed in Table A.1. Evidence of this verification was available and collected (EV13).	**p**
	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		**p**
Transformers: type, manufacturer, isolation, voltage			**p**
Optical isolators: Optical isolator type, isolation, voltage			**p**
Semiconductors:	– Transistors – Integrated circuits – Thyristors – Diodes – Zener diodes	type number, power value and where appropriate, the manufacturer	**p**
Cells and batteries: manufacturer and type number, or IEC designation			**p**
Fuses: manufacturer, type, value			**p**
Insulating materials: specification, dimensions and where appropriate type number			**p**
Connectors (e.g. plugs/sockets and terminals): type number and where appropriate, the manufacturer			**p**
A.4.2	**Printed circuit boards (PCB)**		
A.4.2.1	**Non-populated PCBs**		
PCBs may be accepted with a declaration of conformity (see Annex C). The declaration should state compliance to the purchase documents e.g. a quality plan that lists the factors that together demonstrate conformity of the product. For simple single- or double-			**N/A**

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.		
A.4.2.2	**Populated PCBs**	
• Varnish and coatings should be controlled with respect to the specification of material and effectiveness of the application. • Documented procedures should ensure that the application of varnish and coatings are in conformity with the certificate and/or schedule drawings. • For PCBs the manufacturer should maintain a list of safety critical components used in production (e.g. resistors and Zener diodes) determined during Ex Equipment assessment. The safety critical components placed on the PCB should be verified on a 100 % basis. • Specified distances and clearances on manually assembled PCBs should be verified on a 100 % basis. • This may be conducted by one of the following methods: a) a visual verification; b) for surface mount components, by ensuring correct loading of the "pick and place" machines and a visual verification of correct placement; c) by automatic test equipment (ATE) if the ATE addresses each individual safety critical component and by a visual verification conducted to verify type number of components in shunt Zener diode/diode assemblies. • Where the surface mount component "pick and place" machine selects the component reel based on measuring the component value the measuring function should be calibrated. • Documented procedures should be provided that ensure that workmanship standards are defined with respect to component mounting and soldering. • Documented procedures should ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area and insulation thickness are in conformity with the schedule drawings.	Procedure / work instruction AP-740 (EV8) describes how verification of components used is conducted.	**p**
A.4.3	**Sub-assemblies and assemblies**	
Documented procedures should ensure that production documentation includes all relevant variations to the product design. Production documentation should address all safety critical components, and in the case of encapsulated parts, the compound manufacturer, type, mix and minimum depth. Documented procedures should address the following: a) shelf life and storage of cement and potting compounds; b) mixing; c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion); 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.	Procedure / work instruction 1011-533 (EV14) describes how verification of parts and encapsulating materials is conducted.	**p**

Documented procedures should also ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area, insulation thickness and labels (where appropriate) are fitted. Sealing arrangements should be verified for compatibility with the product's ingress protection rating.			
A.4.4	**Enclosures for Group III or reduced spacing**		
For intrinsically safe apparatus for Group III, or for apparatus that relies on the enclosure for reduced spacing, demonstration of the conformity of the enclosure with the schedule drawings should include the following: a) depths of bore holes and tap holes; b) dimensional requirements for those enclosure parts relevant for sealing effectiveness or mechanical stability; c) insulating coatings and surface conditioning; material, layer thickness. Documented procedures should address the following: a) the gaskets correspond to the quoted specification; b) the sealing elements' effectiveness, e.g. by checking the sealing elements' correct fit. If a gasket's correct fit becomes apparent only after assembly, the imprint could be visually examined, e.g. by use of adequate methods such as use of chalk.		**N/A**
A.4.5	**Routine verifications and tests**		
Procedures for all routine verifications and tests specified in the schedule drawings should be reviewed, along with the results of those verifications and tests, e.g. high voltage tests on complete assemblies or individual components such as transformers, should be controlled by documented procedures and conducted on a 100 % basis unless otherwise permitted.	There were no routine tests or verifications required by the schedule drawings.	**p**
A.4.6	**Intrinsically safe circuits and assemblies incorporated in Ex equipment of other types of protection**		
Where Ex equipment contains intrinsically safe circuits then precautions should be taken as stated in the certificate to ensure that other items listed in the certificate are selected, mounted and installed in accordance with schedule drawings.		**N/A**

Clause	Requirement	Documents or Comments	Verdict
A.5	**Ex e – Increased safety covered by IEC 60079-7**		**N/A**

Clause	Requirement	Documents or Comments	Verdict
A.6	**Ex p – Pressurized equipment covered by IEC 60079-2**		**N/A**

Clause	Requirement	Documents or Comments	Verdict
A.7	**Ex m – Encapsulation covered by IEC 60079-18**		**N/A**

Clause	Requirement	Documents or Comments	Verdict
A.8	Ex o – Liquid immersion covered by IEC 60079-6		N/A

Clause	Requirement	Documents or Comments	Verdict
A.9	Ex q – Powder filling covered by IEC 60079-5		N/A

Clause	Requirement	Documents or Comments	Verdict
A.10	Equipment covered by IEC 60079-15		N/A

Clause	Requirement	Documents or Comments	Verdict
A.11	Ex t – Dust ignition protection by enclosure covered by IEC 60079-31		N/A

Clause	Requirement	Documents or Comments	Verdict
A.12	Ex op – Optical radiation covered by IEC 60079-28		N/A

Clause	Requirement	Documents or Comments	Verdict
A.13	Gas detectors covered by IEC 60079-29		N/A

A.14 – A.18	Information relevant to Non-Electrical Equipment	N/A

Clause	Requirement	Documents or Comments	Verdict
A.14	Ex h – Non-electrical equipment covered by ISO 80079-36		N/A

Clause	Requirement	Documents or Comments	Verdict
A.15	Non-electrical equipment protected by constructional safety “c” covered by ISO 80079-37		N/A

Clause	Requirement	Documents or Comments	Verdict
A.16	Non-electrical equipment protected by control of ignition sources "b" covered by ISO 80079-37		N/A

Clause	Requirement	Documents or Comments	Verdict
A.17	Non-electrical equipment protected by liquid immersion "k" covered by ISO 80079-37		N/A

Clause	Requirement	Documents or Comments	Verdict
A.18	Flame arresters covered by ISO 16852		N/A

Annex B (informative)

Verification criteria for elements with non-measurable paths used as an integral part of a Type of Protection

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4. List of certificates relating to this Quality Assessment Report

4.1 Manufacturers IECEx Certificates of Conformity:

This is the list of all certificates on the current IECEx QAR but only those with a checked box in the first column are for certificates/equipment reviewed during this audit. At the next audit, the verification of equipment and associated documentation should include examples other than those checked at this audit, so that the full range of certified equipment is reviewed over the full audit cycle.

	IECEx Certificate No.	Description of Ex equipment	Ex marking
☒	IECEx FTZU 15.0003X issue 0	Programmable Encoder	Ex ia
☒	IECEx FTZU 19.0002X issue 0	V-AID Valve Controller	Ex ib
☐			

4.2 Manufacturers ATEX EU Type Examination Certificates:

This is the list of all certificates on the current ATEX QAN but only those with a checked box in the first column are for certificates/equipment reviewed during this audit. At the next audit, the verification of equipment and associated documentation should include examples other than those checked at this audit, so that the full range of certified equipment is reviewed over the full audit cycle.

	ATEX Certificate No.	Description of Ex equipment	Ex marking
☒	FTZU 09ATEX0221X Supp 3	Programmable Encoder	Ex ia
☒	FTZU 19 ATEX 0048U Supp 3	V-AID Valve Controller	Ex ib
☐			

4.3 Manufacturers UKEX UK Type Examination Certificates:

This is the list of all certificates on the current UKEX UKQAN but only those with a checked box in the first column are for certificates/equipment reviewed during this audit. At the next audit, the verification of equipment and associated documentation should include examples other than those checked at this audit, so that the full range of certified equipment is reviewed over the full audit cycle.

	UKEX Certificate No.	Description of Ex equipment	Ex marking
☐	N/A		
☐			
☐			

5. Audit non-conformities and observations

See attached Element NCR forms CSF-366A (where applicable).

IECEx/ATEX QUALITY ASSESSMENT REPORT

Report No.:	**TRA-060443-32-00A**	**QAR No.:**	**GB/TRC/QAR15.0002/05**
CTS Ref. No.:	**TBC**	**QAN No.:**	**TRAC13QAN0011 R11**
		UKQAN No.:	**N/A**

NON-CONFORMITY REPORT **NCR No: 01**

Classification:	Minor
Certificate/test report applicable:	All
Clause/Document Ref.	ISO 80079-34 clause 9.2
Corrective action completion date:	2023-01-08

DESCRIPTION OF NON-CONFORMITY
THE INTERNAL AUDIT FOR 2022 HAS NOT BEEN COMPLETED.

Manufacturer Representative		**Assessor:**	
John Parsons		Damian Broadley	
Date:	2022-12-13	***Date:***	2022-12-13

CORRECTIVE ACTION REPORT

To be completed by the manufacturer, and include root cause analysis and a statement describing actual corrective action implemented. Return with evidence via the Element CTS Web portal.

ROOT CAUSE ANALYSIS
Zettlex's intention had been to allocate the internal Audit to the Quality Audit to the incoming quality engineer. The quality engineer declined the post after a 3 month notice period 2 days before joining the company. We had intended to utilise our own internal resource but due to time constraints and availability , Zettlex was advised to use a 3rd party. Sourcing this 3rd party has taken longer than expected.

CORRECTIVE ACTION
Working with Zettlex 3rd party auditing resource and utilising Zettlex in-house capabilities, Zettlex has planned to conduct their ISO9001:2015 and their ISO/IEC 80079-34 audit on the 13th & 14th February 2023. Zettlex will also amend their internal audit schedule to ensure all elements if their ISO9001:2015 and the ISO/IEC 80079-34 are audited annually.

Submitted by Manufacturer Representative		**Approved by Certification Body**		**Accepted by Assessor**	
John Parsons		*B Lythgoe*		*DBroadley*	
Date:	2023-01-25	**Date:**	2023-01-25	**Date:**	2023-01-25