



CONFIDENTIAL

IECEX
QUALITY ASSESSMENT REPORT



IECEX QAR Reference No.: 19.0004/00 – 15.05.2019

Manufacturer : ELIS Plzeň a.s.
Include Address with post code Luční 425/15
301 00 Plzeň, Czech Republic

Production Site(s) audited : ELIS Plzeň a.s. ELIS Plzeň, a.s.
Include Address with post code Soukenická 1557/3 Padochovská 1164/35
320 00 Plzeň 664 12 Oslavany, Czech Republic

Product Description : Inductive flowmeters

Number of Employees : Total: 48 No. involved in Ex products: 20

Scope of Audit : Initial Assessment ☒ Re-Assessment ☐
Surveillance Assessment ☐

List all applicable IECEx Certificates, : Will be added

Electrical equipment with type(s) of protection of : ☒ d, e, i, t
Other (specify)

Audit Team Leader : Ing. Petr Šoltys

Audit Date : 15.05.2019

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- 1 Summary Report
- 2 Audit information
- 3 Documentation Review and Assessment of Implementation
- 4 Observations

Notified Body address / Website information etc/

FTZÚ, s.p., Pikartská 7, 716 07 Ostrava-Radvanice, Czech Republic, www.ftzu.cz



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1. Summary Report

Assessment Summary and Conclusions:

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

The manufacturer is certified according to ISO 9001. The requirements of EN ISO/IEC 80079-34 were added to quality manual and relevant procedures. These requirements are fulfilled in company and in process of production, it was verified by audit.

Audit has done according to audit plan. Company has enabled an access to production sites and offered a requested information and documents.

Company is certified as FTZU 15 ATEX Q 002.

Next Quality Audit due : 04/2020

Non-Conformities

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

NCR No.(s): 01/19

Audit Team Leader Recommendations

(Delete where not applicable)

☒ **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 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

15.5.2019
Audit Team Leader Signature
And Date

Garish
Quality & Certification
Manager

Sign to accept Audit Team Leader
recommendations and QAR



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2. Audit Information

2.1 Scope of Audit:

- Type A initial assessment/reassessment of manufacturer with a certified QMS* ☒
 Type B initial assessment/reassessment of manufacturer without a certified QMS ☐
 Type C surveillance of manufacturer with a certified QMS* ☐
 Type D surveillance of manufacturer without a certified QMS ☐

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

2.2 Audit Criteria : EN ISO/IEC 80079-34

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

2.3 Date(s) and Duration of Audit : 1 day – 15.05.2019

Include total number of auditor days on site

2.4 Composition of Audit Team:

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

2.5 Interviewed Representatives of Manufacturer (Auditee):

Name	Position
Mr. Novak	Quality manager, technical director
Mr. Mareška	Production director
Mrs. Simonova	Sales director
Mr. Zýka	Chef of construction, welding engineer

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

Name of Supplier	Critical item or service provided
Limatherm	housings
Quintex	Cable entries
CRT Electronics	PCB populating



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3. Documentation Review and Assessment of Implementation

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

IECEX 80079-34		Assessed (Y, N or N/A)	Manufacturer's Doc. Ref. List document(s) viewed, with revision status, and Comments List any pertinent details / compliance with requirements of clause	NCR Ref.
4.	Quality Management System			
4.1	General requirements	Y	ISO 9001	
4.2	Documentation requirements	Y	ISO 9001	
4.2.2	Quality Manual	Y	+ requirements of IEC 80079-34	
4.2.3	Control of documents	Y	Technical documentation is controlled, visual difference, procedure SJ 005	
4.2.4	Control of records	Y	10 years archiving, SJ 005	
5.	Management Responsibility			
5.1	Management commitment	Y	ISO 9001	
5.2	Customer focus	Y	ISO 9001	
5.3	Quality Policy	Y	ISO 9001	
5.4	Planning & Quality objectives	Y	ISO 9001, SJ 005	
5.5	Responsibility, authority, internal communications	Y	Responsibility are clearly defined, SJ 005 and document PR001/19, Mr. Novák	
5.6	Management review	Y	+ Ex production, Ex reclamation	
6.	Resource Management			
6.2	Human Resources	N	ISO 9001, no internal Ex training	01/19
6.3	Infrastructure	Y	ISO 9001	
6.4	Work environment	Y	ISO 9001	
7.	Product Realisation			
7.1	Planning of product realisation	Y	ISO 9001	
7.2	Customer requirements	Y	Mr. Novák + Zýka, purch. order review, form Es90133F, user manual	
7.2.3	Customer communication	Y	ISO 9001	
7.3	Design and development	N/A		
7.4	Purchasing	Y	Evaluation of suppliers, input control, there is required a declaration (attestation) of conformity for components, PCB populating with declaration of conformity	
7.5	Identification & traceability	Y	Serial numbers + numbers of components + evidence of customer	
7.6	Control of monitoring & measuring devices	Y	All measuring gauges necessary for Ex verification are calibrated (multimeter, insulation resistance, micrometer)	
8.	Measurement, Analysis & Improvement			
8.2.1	Customer satisfaction	Y	No Ex reclamations	
8.2.2	Internal Audit	Y	Internal audit + ISO 80079-34	



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IECEX 80079-34		Assessed (Y, N or N/A)	Manufacturer's Doc. Ref. List document(s) viewed, with revision status, and Comments List any pertinent details / compliance with requirements of clause	NCR Ref.
8.2.3/4	Monitoring & measurement of processes and product	Y	Dimensional verification, dielectric test, insulation resistance, assembly, functional test, testing procedure	
8.3	Control of non-conforming product	Y	Commitment to inform ExCB (FTZÚ) is defined, SJ 005 + SJ 003	
8.4	Analysis of data	Y	ISO 9001	
8.5	Corrective & Preventive action	Y	ISO 9001	

Annex A: Information relevant to particular types of protection

A.2	General - Material composition of (parts of) enclosures	Y	Declaration of conformity from suppliers	
A.3 Ex d - flameproof enclosures				
A.3.1	Castings	Y	Certified housings (Limatherm)	
A.3.2	Machining	N/A		
A.3.3	Cemented joints and potted assemblies	N/A		
A.3.4	Routine pressure testing	N/A		
A.3.5	Flanged joints	N/A		
A.3.6	Sintered components	N/A		
A.4 Ex i - intrinsic safety				
A.4.1	Components for intrinsically safe products	Y	Input verification	
A.4.2	Printed circuit boards (PCB)	Y		
A.4.2.1	Non-populated PCB's	Y	Declaration of conformity	
A.4.2.2	Populated PCB's	Y	CRT Electronics, drawings Es 200865 and Es 200866	
A.4.3	Sub-assemblies and assemblies	Y	Technical and production documentation	
A.4.4	Tests	Y	El. parameters, insulation resistance	
A.4.5	Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures	Y	Certified housings (Limatherm)	
A.5 Ex e – increased safety				
A.5.1	Ingress protection	Y	Assembly instruction, drawing Es 301454	
A.5.2	Internal wiring and contact integrity	Y	Assembly instruction	
A.5.3	Rotating machines	N/A		
A.5.4	Windings	N/A		
A.5.5	Tests	Y	Dielectric test, insulation resistance, Es 90099Z	
A.6 Ex p – pressured apparatus				
A.6.1	Ingress protection	N/A		
A.6.2	Tests	N/A		
A.7 Ex m – encapsulation				
A.7.1	Production documentation	N/A		
A.7.2	Tests	N/A		



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A.8 Ex o – oil immersion

- Tests N/A

A.9 Ex q – powder filling

A.9.1 Material control N/A

A.9.2 Filling N/A

A.9.3 Ingress protection N/A

A.9.4 Tests N/A

A.10 Ex t – dust protection

Y Approved drawings, visually and mechanical control, tightness test (verification IP)

4. Observations

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

Clause 4

The quality management system has been approved by TUV SUD.

ISO9001 Certificate Registration No. 11.673.798.

Expiration date: 24.06.2021.

Technical documentation is controlled in electronics system IS Helios. Process with modified documentation is described in procedure SJ 005. Visual difference for Ex documentation. No common drawings. Procedure SJ 005 - control of documents, archiving time is 10 years.

Clause 5

Quality management system is ensured by internal and external audits.

Last management review was done in 01.04.2019.

In next management review will be evaluated an external audits and reclamations.

Responsibility and authority are clearly defined in SJ 005 and document PR001/19 (Mr. Novák).

Clause 6

Internal Ex training hasn't been done – 01/19 minor nonconformity.

Procedure SJ 005.

Clause 7

Communication with customer by mail, phone. Review of purchase order Mr. Novák + Zýka). Form Es90133F.

Evaluation of important suppliers is done once a year (quality, price, term). 5.4.2019

Input control – Company requires a declaration of conformity and/or mat. certificate from suppliers (Limatherm, CRT Electronics).

Production – ATEX production until now. Induction sensor (FTZU 12 ATEX 0139U), customer Heinrich Messtechnik for one sensor, purch. order 1470018848 on 2.11.18, review on 6.11.18, production order 31795-315 according to approved documentation, ser. number 59445/18, flow calibration 23.11.18, output control 26.11.18. Records in test protocols (electronic and/or paper form), archiving 10 years.

Identification of product is ensured in test protocol, traceability to customer according to product serial number + ser. numbers of components (sensor, converter) .

To customer is supplied a user manual with special conditions X.

Calibration is controlled by metrolog (Mr. Šíma). All measuring gauges important for testing are calibrated.

Evidence about calibration state of gauges.

Clause 8

Internal audit according to EN ISO/IEC80079-34 has been done on 10.04.2019.

Schedule of audits in 2019 is available.



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Routine tests are done for dimensional verification, el. tests and functional test, records are written to test protocols and archived minimum 10 years.

The label is attached after final test.

Procedures SJ 005 + SJ 003 include a commitment to inform the ExCB and customers about supplied unsafe nonconforming product. (There is no Ex reclamation until today – ATEX production only).



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NONCONFORMITY REPORT

NCR No: 01/19

Classification:	Major / Minor / Observation
Certificate/test report applicable:	
Clause/Document Ref. 80079-34/Test Report/Certificate	6.2.2 Training
Corrective action completion date:	

Description of nonconformity:

Internal Ex training hasn't been done.

Manufacturer Representative:
sign & date

Assessor:
sign & date

Joly 15.5.2019

CORRECTIVE/PREVENTATIVE ACTION REPORT

To be completed by the manufacturer, and include a statement describing actual corrective/preventative action implemented.. Return with evidence. [Address of Notified Body to go here](#)

Manufacturer Representative:
sign & date

Certification Manager:
sign & date

Assessor:
sign & date