



**IECEX
QUALITY ASSESSMENT REPORT**



CONFIDENTIAL

IECEX QAR Reference No.: **SE/SP/QAR07.0002/07**

- Manufacturer** : INFICON AB
Include Address with post code
 Westmansgatan 49
 SE-582 16 Linköping
 Sweden
 Postal address: Box 76, SE-581 02 Linköping, Sweden
- Production Site(s) audited** : See Manufacturer above.
Include Address with post code
- Product Description** : Methane Leak Detector type IRwin SX*, according to
 IECEX ExTR GB/BAS/ExTR16.0156/00
- Number of Employees** : Approx. 25
 No. involved in Ex products: approx. 8
- Scope of Audit** : Initial Assessment
 Re-Assessment
 Surveillance Assessment
 Extra assessment according to
 ISO/IEC 80079-34:2011 for a new product
- List all applicable IECEX Certificates** : ExTR according to "Product Description" above
- Electrical equipment with type(s) of protection of** : is d e m n DIP
 Other (specify)
- Audit Team Leader** : Peter Bremer
- Audit Date** : 18-19 May, 2016
- Valid until** : 2016-12-10
- Internal References** : SP File No.: 6P03396

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SP Technical Research Institute of Sweden

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1. Summary Report

Assessment Summary and Conclusions:

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

Procedures, instructions and technical documentation are available in electronic form on a common network, on a document management system. The staff and management of both INFICON and the supplier Hanza KA Åtvidaberg AB, showed a clear commitment and both companies are actively working on improvements. Suitable considerations of Ex aspects at INFICON, are ensured according to the procedures by the involvement of an appointed experienced Ex-responsible person.

The manufacturer has also a certified quality management system according to Annex IV of the ATEX Directive 2014/34/EU (based on EN ISO/IEC 80079-34:2011) and according to ISO 9001:2015.

Three minor nonconformities were found with respect to the IECEX Quality system requirements. The manufacturer has presented corrective actions which will be verified at the next audit.

Next Quality Audit due : Re-assessment (incl. audit, any corrective measures and successful assessment thereof) and re-certification to be completed before Quality Assessment Report SE/SP/QAR07.0002/05...07 expires 2016-12-10.

Non-Conformities

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

NCR No.(s): Three minor nonconformities No. 1-3 according to the enclosed Nonconformity Report 6P03396:D (Appendix 1).

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

2016-08-18

Peter Bremer
Audit Team Leader, Date

2016-08-18

Lennart Aronsson
**Certification Body Representative,
Date** (report issue date)

*Sign to accept Audit Team Leader
recommendations and QAR*



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)

Extra assessment according to "Scope of Audit" on page 1 above.
 The manufacturer holds an ISO 9001 Certificate issued by SP, according to Appendix 2.

2.2 Audit Criteria

List any other reference documents, against which Audit was conducted in addition to ISO/IEC 80079-34:2011

: The audit was combined with an extra assessment according to EN ISO/IEC 80079-34, to include the new product in an existing certificate type Production Quality Assurance Notification (Certificate No. SP07ATEX4125), according to Annex IV of the ATEX Directive 2014/34/EU. This audit is reported in a separate report.

2.3 Date(s) and Duration of Audit

Include total number of auditor days on site

: 18-19 May 2016: approx 1,75 auditor days on site. The audit included an audit on 19th May at the supplier Hanza KA Åtvidaberg AB on the following site address:
 Örsätterfabriken, SE-597 91 Åtvidaberg, Sweden

2.4 Composition of Audit Team:

Name	Position	Role in Audit (Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)
Peter Bremer	Auditor	Sole Auditor (Team Leader), Technical Specialist

2.5 Interviewed Representatives of Manufacturer (Auditee):

Name	Position
Annci Nylund	Quality Coordinator
Henrik Vennerberg	Quality Manager
Fredrik Enquist	Ex responsible
Viktor Holmquist	Warehouse worker, receiving inspection
Benny Karlén	Production (assembly), testing, service, support
Daniel Granath	Sales, order processing
Mats Hagström	Production Manager, purchase
Bo-Göran Björling	Site Manager, Hanza KA Åtvidaberg AB
Kjell Adolfsson	Quality Manager, Hanza KA Åtvidaberg AB
Bernth Skoglund	Production Manager, Hanza KA Åtvidaberg AB
Anders Johansson	Production preparation, Hanza KA Åtvidaberg AB
Anna Karlsson	Purchase, Hanza KA Åtvidaberg AB
Ingela Fogberg	Inspection, Hanza KA Åtvidaberg AB



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

Example of critical suppliers:

Name of Supplier	Critical item or service provided
Hanza KA Åtvidaberg AB Note: Audit visit was included in the audit. The supplier holds an ISO 9001 Certificate (Appendix 3).	Populated PCBs
Talent Plastics AB	Enclosure
Smålands Polymerteknik AB	Encapsulation
Seritronic A/S	Front window including buttons
Gardner Denver	Pumps
Burkert	Valves
Kingwell	Battery
Ruibo Rubber and Plastic Products Co Ltd	Rubber handle
Freelin-Wade	Hose
ESD Label Solutions	Labels

3. Documentation Review and Assessment of Implementation

During the assessment a number of documents have been reviewed, related to clauses in ISO/IEC 80079-34.

ISO/IEC 80079-34 clauses	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	Y	Nonconformity with respect to clause 4.1 (and to 1 Scope).	PB 01
5 Management responsibility	Y	Nonconformities with respect to clause 5.4.2.	PB 02 PB 03
6 Resource management	Y		
7 Product realisation	Y	7.3.1–7.3.6 not applicable.	
8 Measurement, analysis and improvement	Y		

Annex A: Information relevant to particular types of protection

A.2 Enclosures – General remark	Y
A.3 Ex d - flameproof enclosures	N/A
A.4 Ex i - intrinsic safety	Y
A.4.1 Components for intrinsically safe products	Y
A.4.2 Printed circuit boards (PCB)	Y
A.4.2.1 Non-populated PCBs	Y



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ISO/IEC 80079-34 clauses	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.
A.4.2.2	Populated PCBs	Y	
A.4.3	Sub-assemblies and assemblies	Y	
A.4.4	Tests	N/A	
A.4.5	Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures	N/A	
A.5	Ex e – increased safety	N/A	
A.6	Ex p – pressurized equipment	N/A	
A.7	Ex m – encapsulation	N/A	
A.8	Ex o – oil immersion	N/A	
A.9	Ex q – powder filling	N/A	
A.10	Ex t – Dust ignition protection by enclosure	N/A	
A.11	Gas detectors	N/A	
A.12	Flame arresters	N/A	
Annex B	Verification criteria for elements...	N/A	

4. Observations

The assessment covers extension of the certified quality system according to QAR SE/SP/QAR07.0002/05...06, with production etc of a new product which - at the time of the audit visit - was in the final stage of a type examination intended to result in an IECEX Test Report (ExTR). The assessment of the quality system and the type examination, is related to the explosion protected design by type of protection intrinsic safety "ia" for the product.

The quality management system is documented in electronic form on a common network and appears to work well and is well suited for the activities. The manufacturer's procedures and technical documentation for production and purchase etc, are available in the document management system Centuri. The manufacturer is using SAP as business system, with connections to Centuri. The staff and management of both INFICON and the supplier Hanza KA Åtvidaberg AB, showed a clear commitment and both companies are actively working on improvements. Suitable considerations for Ex aspects at INFICON, are ensured according to the procedures by the involvement of an appointed experienced Ex-responsible person (Fredrik Enquist).

Populated PCB's are provided by the supplier Hanza KA Åtvidaberg AB, which is ISO 9001-certified. The audit included a visit to this supplier.

The manufacturer has also a certified quality management system according to Annex IV of the ATEX Directive 2014/34/EU (based on EN ISO/IEC 80079-34:2011) and according to ISO 9001:2015.

Three minor nonconformities were found with respect to the IECEX quality system requirements, refer to Appendix 1.



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The manufacturer has presented documented corrective and preventive actions with respect to the nonconformities. These actions have been reviewed and considered satisfactory according to Appendix 1. The implementation and effectiveness of the actions, will be followed up at the next audit.

Appendices

1. Nonconformity Report 6P03396:D dated 2016-08-18
2. ISO 9001:2015 Certificate dated 2016-03-21 for INFICON AB
3. ISO 9001:2015 Certificate dated 2016-04-21 for Hanza KA Åtvidaberg AB