



# Notification of recognition of the quality assurance production

Annex IV

(2) Equipment or protective systems intended for use in potentially explosive atmospheres - **Directive 2014/34/EU** 

(3) Notification number:

**SEV 14 ATEX 4111** 

(4) Product:

(1)

Humidity- and temperature transducers and sensors in protection modes intrinsic safety "i", encapsulation "e", increased safety "m"

and dust tightness "t"

A list of the EC-Type Examination Certificates covered by this notification is held by the notified body.

(5) Applicant:

Rotronic AG

Grindelstrasse 6, 8303 Bassersdorf, SCHWEIZ

(6) Manufacturer:

Rotronic AG

Grindelstrasse 6, 8303 Bassersdorf, SCHWEIZ

- (7) Eurofins, notified body number 1258 for Annex IV in accordance with article 17 of the Directive 2014/34/EU, notifies to the manufacturer that he has a quality system which complies with Annex IV and to harmonized standard EN 80079-34:2011.
- (8) This notification is based on audit report no. 18-Ex-0182.01 dated 2018-09-24.
- (9) The results of a regular repeat evaluation of the quality assurance system form part of this notice.
- (10) This notification is valid until 2021-09-24 and can be withdrawn if the manufacturer no longer satisfies the requirements of Annex IV.
- (11) According to article 16 (3) of the Directive 2014/34/EU the notified body assessing the production phase must be indicated by showing the notified body number 1258 of Eurofins beside the CE mark.

Eurofins Electrosuisse Product Testing AG Notified Body ATEX

Jürg Rellstab

**Product Certification** 



### IECEx Quality Assessment Report: CH/SEV/QAR14.0002/03 details

QAR:			
QAR Reference Number *: (automatic numbering)	CH/SEV/QA	R14.0002/03	
Related QARs:	CH/SEV/QA	R14.0002/02 R14.0002/01 R14.0002/00	
Status*:	Issued		
QAR Free Reference Number*:	18-Ex-0182.	01	
Audit Date*: (yyyy-mm-dd)	2018-09-24		
Date of Issue*: (yyyy-mm-dd)	2018-09-26		
Details of change*:	Re-Assessm	nent; Initial assessment under Eurofins Elec	ctrosuisse
Valid until*: (yyyy-mm-dd)	2020-03-09		
Site(s) audited*:	Rotronic AG Grindelstras 8303 Basse SWITZERLA	se 6 rsdorf	
Issuing ExCB*:	SEV - Eurof	ins Electrosuisse Product Testing AG	
Manufacturer*:	Rotronic AG Grindelstras 8303 Basse SWITZERLA	se 6 rsdorf	
Country of Manufacture*:	Switzerland		
Product information*:	Humidity- ar encapsulatio	nd Temperature- transducers and Sensors i on, increased safety and dust tightness	in protection modes intrinsic safety,
Protection concept*:	i, e, m, t		
Related IECEx Certificates: (automatic linking)			
Related Certificates: (manual insertion)	SEV 14 ATE	EX 0107	
Related IECEx Certificates for previous versions:			
	ExCB	CoC and Status	Totals
	SEV		3
		IECEx SEV 14.0002 issue: 0 [Currer	nt]
		IECEx SEV 14.0002 issue: 1 [Currer	nt]
		IECEx SEV 14.0002 issue: 2 [Currer	nt]
			3
Comment:	None		
Attachment:	10 5, 0100	01 QA 2018.pdf	

Last modified: 26.09.2018 09:43:35

Copyright © IEC-IECEx 2018 , Geneva, Switzerland. All rights reserved.









Electrosuisse Product Testing

CONFIDENTIAL

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

ATEX audit report reference no.: 18-Ex-0182.01

Manufacturer : Include Address with post code and country	Rotronic AG Grindelstrasse 6 8303 Bassersdorf SWITZERLAND					
Production site(s) audited: Include Address with post code and country	Rotronic AG Grindelstrasse 6 8303 Bassersdorf SWITZERLAND					
Product description :	Humidity- and Temperature- transducers and Sensors in protection modes intrinsic safety, encapsulation, increased safety and dust tightness					
Number of employees:	Total: 76 No. involved in Ex products: 10					
Scope of audit:	Initial ☑ Surveillance ☐ Re-Assessment ☐					
List all applicable European certificates:	Refer to App	endices 6.	2			
List all applicable IECEx certificates:	Refer to App	endices 6.	3			
Electrical equipment with type(s) of protection of:	i ⊠ d		e ⊠ q □	m ⊠ op □	n 🗌	t 🖂
Non electrical equipment with type(s) of protection of:	fr 🗌 d		с 🗌	b 🗌	р	k 🗌
Specialities	Ventilation	☐ Fuel o	dispensers	Sp Sp	ray systen	าร 🗌
Protection system	Ex proof	☐ Ex pres	ssure relie	f 🗌 Ex	decouplin	ng 🗌
ATEX quality assurance:	Annex IV ⊠	Anne	ex VII 🗌	Annex VI		
Audit team leader:	Thomas Köhntopp					
Audit date:	24th Septem	ber 2018				
Contents:						

- 1 Summary report
- Audit information 2.
- Documentation review and assessment of implementation 3.
- Observations 4.
- Non conformity report 5.
- Appendices (optional)



**Eurofins Electrosuisse Product Testing AG** Swiss Qualification and Certification Body, ATEX Notified Body

Luppmenstrasse 3, 8320 Fehraltorf, SWITZERLAND www.electrosuisse.ch













CONFIDENTIAL

IECEx QAR reference no.:

CH/SEV/QAR14.0002/03

ATEX audit report reference no.: 18-Ex-0182.01

#### 1. **Summary report**

#### Assessment summary and conclusions:

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

Well organized company using an ISO 9001:2015 quality management system certified by SQS. All chapters out of ISO 9001 are included in the management handbook and visible on the intranet.

The ISO 9001:2015 is best introduced and on actual stage. Processes according to the directive 2014/34/EU and to IECEx procedures as well as the responsibilities are clearly defined. The vertical integration is very high and nearly all manufacturing steps can be done internally. Very well trained and educated staffs assure highest quality products.

Next quality audit due:

March 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):

none

#### Audit team leader recommendations

Certification to be issued/maintained

(Check what applicable)

Certification	to	he	issued/maintained*	following	receint	of	satisfactory

eruncation 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

2018-09-24

Audit team leader signature and date

Certification body Sign to accept Lead Assessor recommendations

Manufacturer representative Sign to accept audit team leader recommendations and QAR









CONFIDENTIAL

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

ATEX audit report reference no.: 18-Ex-0182.01

# 2. **Audit Information** 2.1 Scope of Audit: Type A initial / reassessment of manufacturer with a certified QMS\* ISO 9001:2015 Type B initial assessment/reassessment of manufacturer without a certified QMS \_\_\_\_\_\_\_ Type C surveillance of manufacturer with a certified QMS\* ISO 9001:2015 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) Audit criteria: ISO/IEC 80079-34:2018 2.2 Explosive atmospheres - Part 34: Application of quality systems for equipment manufacture 24th September 2018, 1 day assessment

#### **Composition of Audit Team:** 2.4

Date(s) and duration of audit:

Include total number of auditor days on site

2.3

Name	Position	Role in audit (Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)
Thomas Köhntopp	Auditor	Sole Auditor

#### Interviewed representatives of manufacturer (Audited): 2.5

Name	Position
Ms. Susanne Hollmayer	Quality Manager
Mr. Niklaus Devai	Ex responsible person in charge Head
Mr. Daniel Schürmann	Product Manager

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

Name of supplier	Critical item or service provided
Vishay	Zener Diodes
Siba	Fuses
Phoenix Mecano	Enclosures







**CONFIDENTIAL** 

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

ATEX audit report reference no.: 18-Ex-0182.01

#### 3. **Documentation Review and Assessment of Implementation** (For surveillance audits, major document changes only may be reviewed)

EN ISC	D/IEC 80079-34:2011	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	Quality management as well as personnel ensure Ex-compliant manufacturing	
4.2	Documentation requirements			
4.2.1	General	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
4.2.2	Quality Manual	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).  Quality Manual is computer based and on the workstations as actual version available and was reviewed during visit.  Document reviewed: QM18001	
4.2.3	Control of documents	Y	issued 2018-08-15  Drawings for Ex-components are accordingly marked. Changes have to be approved by Ex-responsible person.	
4.2.4	Control of records	Y	All records as requested by this standard are available and retained for at least 11 years as standard for calibration 13 years.	
5.	Management responsibility			
5.1	Management commitment	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
			Document reviewed: "Weisung Organigramm QW_02-001" issued 2018-08-13.	
5.2	Customer focus	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	







**CONFIDENTIAL** 

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

EN ISC	D/IEC 80079-34:2011	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.
5.3	Quality Policy	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
5.4	Planning			
5.4.1	Quality objectives	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
5.4.2	Quality management system planning	Y	Procedures, processes and instructions clearly defined and do ensure compliant fabrication.	
5.5	Responsibility, authority and communications			
5.5.1	Responsibility & authority	Y	Responsibilities and authority defined. Product changes have to be coordinated if required with certification body. Concessions need authorisation of Ex-responsible person.	
5.5.2	Management representative	Y	Ex-responsible person is Mr. Devai.  Document reviewed:  "Stellenbeschreibung Leiter Produktion" issued 2015-08-06.	
5.5.3	Internal communication	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
5.6	Management review			
5.6.1	General	Y	The review takes place every two months. Opportunities and risks are checked including Ex products.  Document reviewed: "Management Review QBQ-18-003" issued 2018-06-13".	
5.6.2	Review input	Y	Reviews do include an overview of management system with Exrelevant aspects.	
5.6.3	Review output	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).  Document reviewed: "Management Review QBQ-18-003" issued 2018-06-13".	







**CONFIDENTIAL** 

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

EN ISO/IEC 80079-34:2011		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.
6.	Resource management			
6.1	Provision of resources	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
6.2	Human resources			
6.2.1	General	Υ	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
6.2.2	Competence, training & awareness	Y	Ex trainings regularly planned for all involved persons once a year.  Document reviewed: "Schulung Mitarbeitende Montage ATEX PS_18-41".	
6.3	Infrastructure	Υ	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate). The necessary infrastructure is in place.	
6.4	Work environment	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate). All necessary resources are available. Work environment is clearly arranged.	
7	Due direct me die etiere			
<b>7.</b> 7.1	Product realisation  Planning of product realisation	Υ	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
7.2	Customer related process			
7.2.1	Determination of requirements related to the product	Υ	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
7.2.2	Review of requirements related to the product	Y	Product distributed via catalogue. Customer has to choose and to know what he orders. Product specifications are available either online or from datasheet.	
7.2.3	Customer communication	Υ	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	







CONFIDENTIAL

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

EN ISC	D/IEC 80079-34:2011	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.
7.3	Design and development			
7.3.1 – 7.3.6	planning, in-, outputs, review, verification and validation	N/A	Not within the scope of this standard.	
7.3.7	Control of design and development changes	Y	Any design changes have to be approved by Ex-responsible or if required also by involved certification body.	
7.4	Purchasing			
7.4.1	Purchasing process	Y	Process clear defined with instructions in all relevant documents.	
7.4.2	Purchasing information	Y	ERP based order. Drawings and test instructions with explosion proof relevant characteristics are delivered if necessary.	
7.4.3	Verification of purchased product	Y	Incoming goods are inspected delivery. Ex relevant aspects are verified by the responsible department.	
7.5	Production & service provision			
7.5.1	Control of production and service provision	Y	Infrastructure and test equipment ensure Ex-compliant end products. Document reviewed: "Fabrikationsablauf Produkte ATEX/IECEx QRF-09-406" issued 2017-05-10.	
7.5.2	Validation of processes for production and service provision	Y	Fulfils the requirements Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
7.5.3	Identification & traceability	Y	Each product has his own name plate with production, position number and manufacturing date. Traceability is, back to the components, possible.	
7.5.4	Customer property	N/A	No such orders accepted.	
7.5.5	Preservation of product	Υ	Each product will be delivered with complete instruction manual.	
7.6	Control of monitoring & measuring equipment	Υ	Each measuring equipment has its own number and is traced by a	







**CONFIDENTIAL** 

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

EN ISC	EN ISO/IEC 80079-34:2011		Manufacturer's Doc. Ref. List document(s) viewed, with revision status, and Comments List any pertinent details / compliance with requirements of clause	NCR Ref.
		,	software tool. The equipment is calibrated external in accredited Calibration Labs.  Reviewed on: Prüfmittel Nr. PM-20416/1a High Voltage tester Certificate No.G23944.0916 issued 2016-09-05	
8.	Measurement, analysis & improvement			
8.1	General	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
8.2	Monitoring & measurement			
8.2.1	Customer satisfaction	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
8.2.2	Internal Audit	Y	Regularly internal audits ensure Excompliant products.  Documents reviewed during visit: "Weisung Auditdurchführung QW 17-42" issued 2018-05-16  Excel files: "Massnahmenplan KJ2018 Q18001" "Auditplanung QX1820"	
8.2.3	Monitoring & measurem. of processes	Υ	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
8.2.4	Monitoring & measurement of product	Y	Each unit undergoes different tests during the manufacturing process as defined in certification documents.  Type plate is attached to housing after successful end tests.	
8.3	Control of non-conforming product	Υ	Recall actions are easily possible by internal documentation.	
8.4	Analysis of data	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
8.5	Improvement			
200 P E	w			







**CONFIDENTIAL** 

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

EN ISO	/IEC 80079-34:2011	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.
8.5.1	Continual improvement	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
8.5.2	Corrective action	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	
8.5.3	Preventive action	Y	Confirmed by the corresponding clause of the ISO 9001:2015 (valid ISO 9001 certificate).	







**CONFIDENTIAL** 

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

Annex A to EN ISO/IEC 80079-34:2011 (IECEx OD005) Information relevant to particular types of protection		Assessed (Y, N or N/A)	Comments List any pertinent details / compliance with requirements of clause	NCR Ref.
A.2 General - Material composition of (parts of) enclosures		Y	Enclosures will go through incoming inspection where requested by certification documentation.	
A.3	Ex d – flameproof enclosures	N/A		
A.4	Ex i – intrinsic safety	Υ		
A.4.1	Components for intrinsically safe prod.	Y	Components will go through incoming inspection where requested by certification documentation.	
A.4.2	Printed circuit boards (PCB)			
A.4.2.1	Non-populated PCB's	Υ	Visual incoming inspection	
A.4.2.2	Populated PCB's	Υ	Assembly and reflow soldering according to internal processes on own, in house equipment.	
A.4.3	Sub-assemblies and assemblies	Υ	Only Enclosure, milled and equipped with cable gland as a subassembly. Undergoes incoming control sample inspection	
A.4.4	Tests	Υ	All tests as requested in the certification documentation and according to the defined manufacturing steps.	
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	Υ	Only certified components used.	
A.6	Ex p – pressured apparatus	N/A		
A.7	Ex m – encapsulation	Υ		
A.7.1	Production documentation	Y	Well documented production documentation.  Document reviewed on workstation.	
A.7.2	Tests	Υ	Visual inspection and check of cure	
A.8	Ex o – oil immersion	N/A		
A.9	Ex q – powder filling	N/A		







CONFIDENTIAL

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

Annex A to EN ISO/IEC 80079-34:2011 (IECEx OD005) Information relevant to particular types of protection		Assessed (Y, N or N/A)	Comments List any pertinent details / compliance with requirements of clause	NCR Ref.
A.10	Ex t – dust ignition prot by enclosure	Υ		
A.10.1	Castings	N/A		
A.10.2	Enclosure parts	Y	Delegated to supplier Phoenix Mecano, control sample testing at incoming inspection.	
A.10.3	Gaskets	Υ	Visual inspection of correct fit.	
A.10.4	Protection devices	N/A		
A.10.5	Cemented and cast enclosure parts	N/A		
A.10.6	Ingress protection	Υ	Visual inspection during end tests.	
A.10.7	Examinations	Υ	Visual inspection during end tests.	
A.11	Gas detectors	N/A		
A.12	Flame arresters	N/A		
	Elizabeth Commence			

Annex ZB to EN ISO/IEC 80079-34:2011 European deviations for non-electrical products according EN 13463-1		Assessed (Y, N or N/A)	Comments List any pertinent details / compliance with requirements of clause	NCR Ref.
ZB	Annex ZB	N/A		









CONFIDENTIAL

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

NCR No.: None

ATEX audit report reference no.: 18-Ex-0182.01

#### **Observations** 4.

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

Well organized company, achieving very high quality standards. Update to ISO 9001:2015 is done in 2018. No nonconformities reported. The company is keeping their own high quality demands and continuously expands the internal test equipment and capacities.

The quality system and the changes due to the introduction of the ISO 9001:2015 are checked and explained by Ms. Hollmayer and Mr. Devai as Ex representative.

The Processes of Management review, management of resources, training and product realization are checked on documentation, work instruction and process description during the interview.

The last issued management review and internal audit documentation was checked.

Training of employees involved in production of Ex products was checked on documentation.

The manufacturing process was checked on a sample order from incoming goods to the storage and shipping of the final product. Measurement equipment and process documentation are up to date.

### Positive findings:

The items with potential of improvement of the last audit are all checked and have been introduced into the quality management system.

Non Conformity report 5.

Page 12 of 13







**CONFIDENTIAL** 

IECEx QAR reference no.: CH/SEV/QAR14.0002/03

ATEX audit report reference no.:

18-Ex-0182.01

## Appendices (optional) Additional assessor notes 6.

### **6.1 List of Documents**

Title	Document No.	Revision	Date
Weisung Organigramm	QW_02-001	1	2018-08-13
Mitteilung MM-Review	QBQ-18-003	1	2018-06-13
Richtlinie Ziele und Messgrössen KJ18	QRG-20-404	17	2018-06-13
Richtlinie Fabrikationsablauf Produkte	QRF-09-406	2	2017-05-10
ATEX/IECEx			7,744
LK-PRODUKTIONSAUFTRAG	Pa-Nr.: 0 <sup>E</sup> -01050733-0050		2018-08-10
Calibration Certificate – Withstanding	G23944.0917		2018-09-05
Voltage Tester			

### **6.2 List of ATEX Certificates**

Certificate No.	Applicable type of protection	Revision
SEV 14 ATEX 0107	eb, ia, mb, tb	2

#### 6.3 List of IECEx Certificates

Title	Applicable type of protection	Issue
IECEx SEV 14.0002	eb, ia, mb, tb	2