

 E&E	IECEX QUALITY ASSESSMENT REPORT	 	
Report No.:	20CH-01412.X05	QAR No.:	CH/SEV/QAR16.0001/04

Project No.	20CH-01412.X05		
Ex QMS Certificates	SEV 16 ATEX 4130		
Manufacturer Include Address with post code	Wandfluh Hydraulik + Elektronik AG Helkenstrasse 13 3714 Frutigen SWITZERLAND		
Production Site(s) audited Include Address with post code	Wandfluh Hydraulik + Elektronik AG Helkenstrasse 13 3714 Frutigen SWITZERLAND		
Product Description	Hydraulics and Electronics whole company		
Employee count	Total onsite: 240 Total involved in Ex products: 30		
Scope of Audit	Initial Assessment <input type="checkbox"/>	Surveillance Assessment <input type="checkbox"/>	
	Re-Assessment <input checked="" type="checkbox"/>	Special Assessment <input type="checkbox"/>	
Scheme	IECEX <input checked="" type="checkbox"/>	ATEX <input checked="" type="checkbox"/>	
Ex equipment with type(s) of protection	d <input checked="" type="checkbox"/> e <input type="checkbox"/> h <input type="checkbox"/> i <input checked="" type="checkbox"/> m <input type="checkbox"/> n <input type="checkbox"/> p <input type="checkbox"/> t <input checked="" type="checkbox"/> op <input type="checkbox"/> q <input type="checkbox"/>		
Audit Team Leader	Thomas Köhntopp		
Audit Date	2020-10-14		

Contents:

- 1 Summary Report
- 2 Audit information
- 3 Documentation Review and Assessment of Implementation
- 4 Certificate List
- 5 Audit Non-Conformities and Observations

NOTE: whilst some parts of this form / template are optional there is an expectation that all ExCBs will

- use the form as published
- only add content, and
- not ignore the non-optional aspects

IECEX ExCB**E&E**

Eurofins Electric & Electronic Product
Testing AG
ATEX Notified Body 1258
Luppmenstrasse 3, 8320 Fehraltorf,
SWITZERLAND



 	IECEX QUALITY ASSESSMENT REPORT	 	
Report No.:	20CH-01412.X05	QAR No.:	CH/SEV/QAR16.0001/04

1. Summary Report

Assessment Summary and Conclusions:

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

All requirements according to EN ISO/IEC 80079-34 and according to the Directive 2014/34/EU annex IV fulfilled.

NO nonconformities listed.

Issuing of the ATEX QAN is recommended.

Next Quality Audit due : April 2022

Non-Conformities (refer to section 6)

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


NCR No.(s): 0

OBS 0

Audit Team Leader Recommendations

(Delete where not applicable)

- Notification / Certification to be issued/maintained** once satisfactory technical assessment of the product is completed and a test report is issued
- Notification / 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
- Notification / 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.
- Notification / Certification to be refused/suspended*** A further complete assessment to be conducted
- Notification / Certification to be refused/suspended*** Close the application/withdraw the notification and inform the Scheme Administrator or other Notified Bodies.


2020-10-15

Audit Team Leader Signature


2020-10-19

ExCB Technical Reviewer

 E&E	IECEX QUALITY ASSESSMENT REPORT	 	
Report No.:	20CH-01412.X05	QAR No.:	CH/SEV/QAR16.0001/04

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

List any other reference documents, against which Audit was conducted

- ISO/IEC 80079-34, Ed. 2.0:2018
- Other applicable reference Standards
- : Other applicable reference Standards
- Other applicable reference Standards

- 2.3 Date(s) and Duration of Audit** : 2020-10-12, 1 day assessment with two auditors (2 auditor days)
 Include total number of auditor days on site

2.4 Certified Quality System

ISO 9001 Certificate No	Certified by	Expiry date	Scope
10632	SQS	2021-03-11	Hydraulics and Electronics whole company

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.

At Wandfluh Hydraulik + Elektronik AG the last surveillance audit took place on 2020-03-18 to 2020-03-19. No non-conformities are listed.

2.5 Composition of Audit Team:

Name	Position	Role in Audit (Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)
Thomas Köhntopp	QAR Auditor	Team Leader
Christian Ettlin	QAR Auditor	Auditor