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UKCA Surveillance Assessment Report

Certificate **CML 22UKQAN15178**

Applicant **Wandfluh Hydraulik + Elektronik AG**

Report **R16979A/00**

Date (of issue) September 2023

1 Introduction

1.1 Summary review

External ExQA Audit report reference	:	20CH-01412.X07- CH/SEV/QAR16.0001/06	
Certification Body name	:	SEV - Eurofins Electric & Electronic Product Testing AG	
Audit Scope	:	UK QAN	<input checked="" type="checkbox"/>
External audit report stage	:	Initial Assessment (Stage 1/Stage 2)	<input type="checkbox"/>
		Re-Assessment	<input checked="" type="checkbox"/>
		Surveillance Assessment	<input type="checkbox"/>
		Change to approval	<input type="checkbox"/>
Manufacturer Include Address with post code	:	Wandfluh Hydraulik + Elektronik AG Helkenstrasse 13 3714 Frutigen Switzerland	
Authorised person	:	Tobias Krause	
Contact Email/Phone	:		
Production Site(s) audited Include Address with post code	:	Same as above	
Approx No of employees	:	Total applicable to management system: 264 Total applicable to Ex: 30	Total applicable to management system: Total applicable to Ex:
Scope of operations (business functions) Business activities, product/service Language/s	:	Development, production, and sales as well as trading of hydraulic components, Hydraulic systems, and associated electronics	
Changes to scope (surveillance/reassessment only)	:	N/A	
Product Description	:	Hydraulics and Electronics whole company	

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Electrical equipment with type(s) of protection of	:	d <input checked="" type="checkbox"/> p <input type="checkbox"/> q <input type="checkbox"/> o <input type="checkbox"/> e <input type="checkbox"/> is <input checked="" type="checkbox"/> v <input type="checkbox"/> n <input type="checkbox"/> m <input type="checkbox"/> s <input type="checkbox"/> op <input type="checkbox"/> t <input checked="" type="checkbox"/> Trace heating <input type="checkbox"/> Protective system <input type="checkbox"/> Non-elec <input type="checkbox"/> Other (specify) <input type="checkbox"/>
Technical areas	:	Electronics <input type="checkbox"/> Diesel engines <input type="checkbox"/> Gas detectors <input type="checkbox"/> Moulding <input type="checkbox"/> Trucks <input type="checkbox"/> Func S (prod) <input type="checkbox"/> Machining <input type="checkbox"/> Motors <input type="checkbox"/> Func S (soft) <input type="checkbox"/> Fabrication <input type="checkbox"/> Luminaires <input type="checkbox"/> Assembly <input checked="" type="checkbox"/> Dispensers <input type="checkbox"/> Casting <input type="checkbox"/>
Assessor	:	Afsaneh Jafari Quality Manager/ Ex QA Certification Officer Eurofins CML Desktop Reviewer
Audit Date	:	26/09/2023
Planned date of next audit	:	September 2024

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1.2 List of Certificates

Product Description	ATEX Certificate number	UKCA Certificate number
Solenoid coil type M*Z45-***-***	SEV 16 ATEX 0127 X	CML 22UKEX2141X
Solenoid type MKY45/18x60-**/L *****#	BVS 11 ATEX E 037 X	CML 22UKEX1157X

1.3 Critical suppliers

See external Ex QA audit report.

2 Assessment Summary and Conclusions

2.1 Summary

This report addresses Eurofins CML desktop review against SEV audit reports number 20CH-01412.X07, and overall assessed against the requirement of UK SI 2016 No. 1107, to make sure Wandfluh. A Quality system continuing meet the requirement of this UK regulation, sample document check during this assessment by Eurofins CML assessor which listed below as,

No Significant change reported by SEV since last assessment.

No finding has been raised during initial assessment to be review in this assessment.

One non-conformity and one observation has been raised by SEV during re-assessment visit. Which considered closed by SEV.

Actual label for production Nr: 232509254 CML certificate number CML 22UKEX1157X verified and found correct UKCA marking has been affixed to the product.

Operation manual for CML certificate number CML 22UKEX1157X verified and found included special condition of Use and UKCA information.

As a result of this review no- finding raise for Wandfluh. In conclusion, in the absence of any non-conformity Wandfluh Continue to conform with (UK SI 2016 No. 1107) as UK regulation, continued certification of UK quality assurance is recommended to Eurofins CML.

2.2 Outstanding Findings/Non-conformities

There are no outstanding findings/non-conformities.

2.3 ISO 9001 Certification

The manufacturer has the following ISO 9001 certification. *(if not ISO 9001 certified then the applicable clauses of ISO 80079-34 shall be fully addressed and this section is to be removed)*

ISO 9001 certificate No	Certified by	Expiry date	Scope
10632	SQS	10/03/2024	Development, production, and sales as well as trading of hydraulic components, Hydraulic systems and associated electronics

2.3.1 ISO 9001 Certification review

A copy of the ISO 9001 certificate was provided and was deemed to be acceptable.

2.4 Recommended Audit Interval

The planned date of the next audit by the external certification body is accepted.


2.5 CML Recommendation

<input type="checkbox"/>	Certification to be issued/maintained	Once satisfactory technical assessment of the product is completed, and a test report is issued
<input checked="" type="checkbox"/>	Certification to be issued/maintained	No findings have been raised
<input type="checkbox"/>	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
<input type="checkbox"/>	Certification to be issued/maintained	Following a satisfactory follow-up visit and verification that corrective actions have been effectively documented and implemented, and audit report issued.
<input type="checkbox"/>	Certification to be issued/maintained	Following submission of satisfactory proposed corrective actions and technical review. Corrective action to be formally verified at next visit.
<input type="checkbox"/>	Certification to be refused/suspended	A further complete assessment to be conducted
<input type="checkbox"/>	Certification to be refused/suspended	Close the application/withdraw the notification and inform the Scheme Administrator

2.6 Signatures

2.6.1 Assessor

By signing the assessor confirms acceptance of the external Ex QA report

Assessor (name):	Afsaneh Jafari
Signature:	
Date:	26/09/2023

2.6.2 Certification Decision

By signing this report, the certification decision maker agrees with the recommendation made by the assessor to accept the external Ex QA report in support of certification.




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Certification Decision maker (name):	Andy Smith
Signature:	
Date:	02/10/2023

2.7 Date of next Audit (to be completed by Eurofins CML)

Date:	September 2023
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3 Audit information

3.1 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
- Type E** initial assessment/surveillance/reassessment for ISO 9001 only

* 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)

3.2 Audit criteria

The following documents were used as reference during the audit (*tick as appropriate*):

<input checked="" type="checkbox"/>	ISO/IEC 80079-34:2018
<input type="checkbox"/>	ISO 9001:2015
<input type="checkbox"/>	Directive 2014/34/EU (ATEX)
<input checked="" type="checkbox"/>	BS EN ISO/IEC 80079-34:2020/ UK SI 2016 No. 1107
<input type="checkbox"/>	Client processes and documentation described in management system
<input type="checkbox"/>	(Any other documentation, amend as necessary)

- End of report