

- Manufacturer** : HB Products A/S, Bøgekildevej 21, DK-8361 Hasselager, Denmark  
Include address with post code
- Production Site(s) audited** : HB Products A/S, Bøgekildevej 21, DK-8361 Hasselager, Denmark  
Include address with post code
- Product Description** : Position and Level Sensors  
IECEX code: Ex ib IIC T5, Ex ib IIC T5/T6 Gb, Ex ib IIC T6...T1 Gb  
ATEX code: II 2G EEx ib IIC T5, II 2G Ex ib IIC T5/T6 Gb,  
II 2G Ex ib IIC T6...T1 Gb  
Refer to actual IECEx ExTRs, and EC- and EU-Type Examination  
Certificates, for details and ambient temperatures
- Number of Employees** : Total: Approx. 19                      No. involved in Ex products: 7
- Scope of Audit** : Initial Assessment                        
Re-Assessment      
Surveillance Assessment
- Audit according to Annex VII of the ATEX Directive 2014/34/EU (applied  
standard: EN ISO/IEC 80079-34:2011) and according to the IECEx System  
(applied standard: ISO/IEC 80079-34:2011).  
Certificates for the QMS: SP13ATEX7150 (ATEX PQAN) and  
SE/SP/QAR13.0001/02...03 (IECEX QAR)
- Product Certificates** : See List of product certificates 8P09049:C (Appendix 2)
- Electrical equipment with type(s) of protection of** : is  (gas) d  e  m  n  t   
Other (specify)   
For details, see certificates according to List of product certificates 8P09049:C  
(Appendix 2)
- Audit Team Leader** : Klaus M. Hansen
- Audit Date** : 2019.01.24
- IECEX QAR valid until** : 2022.02.15 (same as for the ATEX PQAN)
- Internal References** : RISE File No: 8P09049

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its name to RISE Research Institutes of Sweden AB in 2017.

## 1. **Summary Report**

The latest update of the quality handbook is dated January 7<sup>th</sup> 2019, and signed by the administrative Manager. The quality handbook has been updated to reflect the new requirements in ISO 9001:2015. The existing ISO 9001:2015 certificate will expire in March 2019 – Re-certification has been done successfully and a new certificate is expected to be issued within 30 days.

A new ATEX EU-Type Examination Certificate and a new IECEX Ex Test Report (ExTR) are to be added to the PQAN and QAR respectively. The product is a Capacity Liquid sensor with the ATEX marking; II 2 G Ex ib IIC T6...T1

Michael Elstrøm and Martin Mozart Ernst are both appointed IECEX/ATEX authorised persons. The responsibilities and authorities are clearly described in quality manual chapter 5.1.

HB Products A/S has demonstrated EN ISO/IEC 80079-34:2011 understanding and implementation as well as good understanding of the importance of the efficiency and effectiveness of relevant IECEX / ATEX processes. The corrective and preventive action system is effectively implemented and all findings raised during previous IECEX / ATEX audit have been closed effectively. The internal audit system is effectively implemented and the found findings are assessed as relevant for the improvement of the system. The management review system is effectively implemented.

At the latest IECEX / ATEX audit dated 10.08.2017, one nonconformity (KH01) and 1 observation (KH02) was raised. The implementation of the corrective action for the finding has been verified and accepted at this audit. Also the one observation has been addressed.

**As info:** A new ISO/IEC 80079-34:2018 has been published 2018-08-30. Deadline for implementation is 2020-08-30.

**Next Quality Audit due** : **August 2020** – Surveillance audit to be done not later than 2020-08-15 (18 months after re-issuance of Product Quality Assurance Notification (PQAN) for ATEX and Quality Assessment Report (QAR) for IECEX).

### **Non-Conformities**

No non-conformities raised, but for info an observation is issued

### **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



31.01.2019

Klaus M. Hansen  
Audit Team Leader Signature, Date

8.2.2019

Peter Bremer  
Certification Officer Signature,  
Date (report issue date)  
*Sign to accept Audit Team Leader  
recommendations and report*

**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 .....

The manufacturer holds an ISO 9001:2015 certificate (see to Appendix 3), with the following scope:  
*The design, manufacture and sale of position and level sensors*

**2.2 Audit Criteria** : EN ISO/IEC 80079-34:2011 (ATEX)  
 ISO/IEC 80079-34:2011 (IECEX)  
 (incl. applicable parts of ISO 9001:2008)  
*List reference documents, against which Audit was conducted*

**2.3 Date(s) and Duration of Audit** : 24.01.2019, 1 auditor day  
*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)
Klaus M. Hansen	Lead Auditor	Lead auditor, Technical Specialist

**2.5 Interviewed Representatives of Manufacturer (Auditee):**

Name	Position
Michael Elstrøm	Quality Manager / Administrative Manager / Authorised Person
Martin Mozart Ernst	R&D and PTA Director, Partner / Authorised Person
Rikke Damsø	Purchasing
Jan Thorn	Production / Service
Henrik Poulsen	Production

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

Name of Supplier	Critical item or service provided
LM Project.	Printed Circuit Boards
Pepperl & Fuchs	Barriers
Stockmeier	Compound
Bjerregaard	Metal Enclosure
Microlod	Nipples
Metalica	Metal tubes

**3. Documentation Review and Assessment of Implementation**

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

EN ISO/IEC 80079-34:2011 and ISO/IEC 80079-34:2011 clauses		Assessed (Y, N or N/A)	Manufacturer's Doc. Ref. List document(s) viewed, with revision status, and <b>Comments</b> List any pertinent details / compliance with requirements of clause	NCR Ref.
<b>4. Quality Management System</b>				
4.1	General requirements	Y	Quality system, procedures, instructions and registrations	
4.2	Documentation requirements	Y	“	
4.2.2	Quality Manual	Y	“	
4.2.3	Control of documents	Y	“	
4.2.4	Control of records	Y	“	
<b>5. Management Responsibility</b>				
5.1	Management commitment	Y	“	
5.2	Customer focus	Y	“	
5.3	Quality Policy	Y	“	
5.4	Panning & Quality objectives	Y	“	
5.5	Responsibility, authority, internal communications	Y	“	
5.6	Management review	Y	“	
<b>6. Resource Management</b>				
6.2	Human Resources	Y	“	
6.3	Infrastructure	Y	“	
6.4	Work environment	Y	“	
<b>7. Product Realisation</b>				
7.1	Planning of product realisation	Y	“	
7.2	Customer requirements	Y	“	
7.2.3	Customer communication	Y	“	
7.3.1-6	Design and development	N/A		
7.3.7	Control of design and development...	Y	“	
7.4	Purchasing	Y	“	
7.5	Identification & traceability	Y	“	
7.6	Control of monitoring & measuring devices	Y	“	
<b>8. Measurement, Analysis &amp; Improvement</b>				
8.2.1	Customer satisfaction	Y	“	
8.2.2	Internal Audit	Y	“	
8.2.3/4	Monitoring & measurement of processes and product	Y	“	
8.3	Control of non-conforming product	Y	“	
8.4	Analysis of data	Y	“	
8.5	Corrective & Preventive action	Y	“	

EN ISO/IEC 80079-34:2011 and ISO/IEC 80079-34:2011 clauses	Assessed (Y, N or N/A)	<b>Manufacturer's Doc. Ref.</b> List document(s) viewed, with revision status, and <b>Comments</b> List any pertinent details / compliance with requirements of clause	NCR Ref.
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**Annex A: Information relevant to particular types of protection**

<b>A.2</b>	<b>Enclosures – General remark</b>	Y	“
<b>A.3 Ex d - flameproof enclosures</b>			
A.3.1	Verification	N/A	
A.3.2	Castings	N/A	
A.3.3	Machining	N/A	
A.3.4	Cemented joints and potted assemblies	N/A	
A.3.5	Routine pressure testing	N/A	
A.3.6	Flanged joints	N/A	
A.3.7	Elements, with non-measurable...	N/A	
<b>A.4 Ex i - intrinsic safety</b>			
A.4.1	Components for intrinsically safe products	Y	“
A.4.2	Printed circuit boards (PCB)	Y	“
A.4.2.1	Non-populated PCB's	Y	“
A.4.2.2	Populated PCB's	Y	“
A.4.3	Sub-assemblies and assemblies	Y	“
A.4.4	Tests	Y	“
A.4.5	Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures	N/A	
<b>A.5 Ex e – Increased safety</b>			
A.5.1	Ingress protection	N/A	
A.5.2	Internal wiring and contact integrity	N/A	
A.5.3	Rotating machines	N/A	
A.5.4	Windings	N/A	
A.5.5	Terminal boxes	N/A	
A.5.6	Cable glands, terminals and other...	N/A	
A.5.7	Routine verifications and tests	N/A	
<b>A.6 Ex p – Pressured apparatus</b>			
A.6.1	Ingress protection	N/A	
A.6.2	Components and manufacturing...	N/A	
A.6.3	Components, constructional...	N/A	
A.6.4	Routine verifications and tests	N/A	
<b>A.7 Ex m – Encapsulation</b>			
A.7.1	Production documentation	N/A	
A.7.2	Routine verifications and tests	N/A	
<b>A.8 Ex o – Oil immersion</b>			
<b>A.9 Ex q – Powder filling</b>			
A.9.1	Material control	N/A	
A.9.2	Filling	N/A	

EN ISO/IEC 80079-34:2011 and ISO/IEC 80079-34:2011 clauses		Assessed (Y, N or N/A)	Manufacturer's Doc. Ref. List document(s) viewed, with revision status, and <b>Comments</b> List any pertinent details / compliance with requirements of clause	NCR Ref.
A.9.3	Ingress protection	N/A		
A.9.4	Routine verifications and tests	N/A		
<b>A.10 Ex t – Dust ignition protection by enclosure</b>				
A.10.1	Casting	N/A		
A.10.2	Enclosure parts	N/A		
A.10.3	Gaskets	N/A		
A.10.4	Protection devices	N/A		
A.10.5	Cemented and cast enclosure parts	N/A		
A.10.6	Ingress protection	N/A		
A.10.7	Examinations	N/A		
<b>A.11</b>	<b>Gas detectors</b>	N/A		
<b>A.12</b>	<b>Flame arresters</b>	N/A		
<b>Annex B</b>	<b>Verification criteria for elements...</b>	N/A		
<b>Annex ZA<sup>*)</sup></b>	<b>Normative references...</b>	Y		
<b>Annex ZB<sup>*)</sup></b>	<b>Information relevant to...</b>	N/A		

<sup>\*)</sup> Applicable for EN ISO/IEC 80079-34 but not for ISO/IEC 80079-34

#### 4. Observations

Review of the quality system (Manual / procedures / instructions)

- Quality handbook, procedures, instructions and registration schemes are updated continuously and last on January 7<sup>th</sup> 2019. The quality system is maintained, and improvements have been done since last ATEX/IECEX assessment. The quality handbook is updated to reflect the new requirements in ISO 9001: 2015
- The organisation chart is constantly updated and does reflect the Authorised persons.
- All internal non-conformities are registered in non-conformity reports (4/8-d reports) and closed according to time scales described in procedure. The external non-conformities are handled in special data base.

Review of specific IECEX / ATEX Certificates to determine the safety related aspects.

- New ATEX EU Type Examination Certificate and a new IECEX Test Report are to be added to the PQAN and QAR respectively. The product is a Capacity Liquid sensor with the marking; II 2 G Ex ib IIC T6...T1 (for details please see the actual certification documents). The specified conditions for safe use are included in the User manual which is sent to the customer with the product.

Document and data Control.

- HB Products A/S has a very good implemented system for document and data control, which secure that all relevant IECEX / ATEX documents are securely stored and filed for at least 10 years after end of production and delivery of the products.

Production (including Monitoring and Measurements of IECEX / ATEX products).

- The moulding process was audited. Components used were all clearly marked with expiry dates and used accordingly. The process is well defined and described.
- All production personnel have a good knowledge of IECEX / ATEX requirements, and the critical aspects of the Ex products manufactured. The labelling of IECEX / ATEX products is done after final tests. The requirements from EN ISO/IEC 80079-34:2011 and ISO/IEC 80079-34:2011 are observed continuously during the production.

Calibration.

- Calibration of equipment is done yearly for selected measuring equipment. The calibration is done using an externally calibrated (by Trescal (DANAK accredited)) multimeter. Good registrations in accordance with requirements in 80079-34 chapter 7.6 were seen during the audit.

Purchasing (including Incoming goods inspection).

- Purchasing are done by purchasing department and controlled very well through purchase orders including all relevant purchasing requirements from EN ISO/IEC 80079-34:2011 and ISO/IEC 80079-34:2011.
- All received items (safety components) are checked on a 100% basis for compliance with "certified" Scheduled drawings and other quality aspects.

Customer Related Processes (sales).

- Sales are handled very well, and it is ensured that customer requirements are compatible with the IECEX certificates, and the EC- and EU-Type examination certificates.

Management review, Internal audits, Corrective / Preventive Actions

- Management review is carried out twice a year (Quality Committee meetings) and the latest on November 8<sup>th</sup> 2018. These meetings contain issues regarding IECEX / ATEX requirement and includes an overall statement concerning the effectiveness of the quality system with respect to products intended for use in potentially explosive atmospheres.
- Internal audits are planed yearly, and audits are performed according to the plan. Last internal audit was carried out in December 2018 by external consultant Anders Chr. Haahr from Milestone Pro ApS.

## Appendices

1. Nonconformity Report (NCR) 8P09049:B
2. List of product certificates 8P09049:C
3. ISO 9001:2015 certificate



## Non-conformity Report (NCR)

**Audit date:** 2019-01-24

**Company (manufacturer):** HB Products A/S

**Major nonconformity (S):** New follow-up audit is required, verifying that corrective actions have been effectively documented and implemented.

**Minor nonconformity (M):** Satisfactory documentary evidence supporting effective corrective action, to be presented within 6 weeks. That the corrective actions have been effectively documented and implemented shall be verified at the next audit.

**Observations (N):** No immediate action needed.

No.	Description of nonconformity/observation	Where was the nonconformity found	Assessment: - Major (S) - Minor (M) - Observation (N)	Section, standard: - EN ISO/IEC 80079-34:2011 (EN) - ISO/IEC 80079-34:2011 (ISO/IEC) - ISO 9001:2008 (ISO)	Corrective action presented by the company and root cause for the nonconformity	Lead auditor comments
KH 01	A new version of <b>ISO/IEC 80079-34:2018</b> has been published 2018-08-30. Deadline for implementation is 2020-08-30.	Meeting room – Quality handbook	Observation (Just for information)			No immediate action needed

## List of product certificates

**Audit date:** 2019.01.24

**Company (manufacturer):** HB Products A/S

**Certificates:** - IECEx Test Report (ExTR) and IECEx Certificate of Conformity (CoC) according to the IECEx system  
 - EC-Type Examination Certificate according to ATEX Directive 94/9/EC  
 - EU-Type Examination Certificate according to ATEX Directive 2014/34/EU

### ATEX

EU/EC-Type Examination Certificate no/issue (issue date)	Report no/issue	Comment <sup>1)</sup>
Demko 05 ATEX 135657 Issued 2005.12.07 (Schedule updated 2007.03.19)	135657-05	Long Stroke/Short Stroke displacement sensor
-	-	-
TÜV 16ATEX173252X/01 (170119)	17 203 192526 Dated 2017.01.19	Long stroke transmitter: SA96DX-I/Ex Short stroke transmitter: SLCD-M1/25/Ex
TÜV 18ATEX226168X/00 (181212)	18 203 192526 Dated 2018-12-12	<b>NEW</b> Liquid sensor type HBCS-EX01-X resp. HBCS-EX01-X_PT1000

### IECEx

IECEx CoC no/issue (issue date)	IECEx ExTR	Comment <sup>2)</sup>
IECEx ULD 06.0009/1 (130802)	DK/ULD/ExTR06.0007/00...01	Long troke/Short Stroke displacement sensor
IECEx TUN 16.0001X/0 (161107)	DE/TUN/ExTR16.0024/00	Long stroke transmitter: SA96DX-I/Ex Short stroke transmitter: SLCD-M1/25/Ex
IECEx TUN 16.0001X/1 (170126)	DE/TUN/ExTR16.0024/01	Transmitters as specified above.
IECEx TUN 18.0027X (190110)	DE/TUN/ExTR18.0037/00	<b>NEW</b> Liquid sensor type HBCS-EX01-X resp. HBCS-EX01-X_PT1000

<sup>1)</sup> E.g. product type designation or type of explosion protection

<sup>2)</sup> E.g. product type designation or type of explosion protection

**Note:** New or revised EC/EU-Type Examination Certificates, IECEx CoCs or ExTRs (due to e.g. new/changed certified products or new/revised schedule drawings), not covered by previous audits, are underlined and/or marked with **yellow**.

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## HB Products A/S

Main Site: Bøgekildevej 21, 8361 Hasselager, Denmark  
Chamber of commerce: 26693934

has been registered by Intertek as conforming to the requirements of:

## ISO 9001:2015

The management system is applicable to:

The design, manufacture and sale of position and level sensors.

**Certificate Number:**

0043279-01

**Initial Certification Date:**

08 March 2004

**Date of Certification Decision:**

23 February 2018

**Issuing Date:**

23 February 2018

**Valid Until:**

07 March 2019



Accred. no. 1639  
Certification of  
Management  
Systems  
ISO/IEC 17021-1

**Thomas Andersson**

MD, Business Assurance Nordics

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