



# IECEX Quality Assessment Report

**INTERNATIONAL ELECTROTECHNICAL COMMISSION**

**IEC SCHEME FOR CERTIFICATION TO STANDARDS FOR SAFETY OF ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERES (IECEX-System)**

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**Report No** : DE/TUR/QAR/16.0010/01  
01 220 1609017 (ATEX)

**Date of Issue** : 2019-05-10

**Valid until** : 2022-07-06


**Product Category** : Explosion-proof Solenoid  
Type "d" "t"

**Applicant** : Ningbo HOYEA Machinery Manufacture Co., Ltd.  
Zhoujia, Hengxi town, Yinzhou district, Ningbo, Zhejiang, P.R. China

**Manufacturing Locations** : Ningbo HOYEA Machinery Manufacture Co., Ltd.  
Zhoujia, Hengxi town, Yinzhou district, Ningbo, Zhejiang, P.R. China

**Approved for issue on behalf of the IECEx Certification Body** : Andreas Maschke

**Position** : Head of Certification Body

**Signature** : 

**Date** : 2019-05-10

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Quality Report issued by:

**TÜV Rheinland Industrie Service GmbH**  
**Am Grauen Stein**  
**51105 Köln**

 **TÜVRheinland®**  
Precisely Right.

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**CONFIDENTIAL**  
**Audit Report No: DE/TUR/QAR/16.0010/01**  
**01 220 1609017 (ATEX)**  
TÜV Rheinland Industrie Service GmbH



**Manufacturer (auditee)** : Ningbo HOYEA Machinery Manufacture Co., Ltd.  
**Address** : Zhoujia, Hengxi town, Yinzhou district, Ningbo, Zhejiang, P.R. China

**No. of employees** : 175  
*include the total number of employees on site and those involved in production of Ex products*

**Scope of audit** : initial assessment  reassessment  surveillance   
*List all applicable IECEx Test Reports (or attach copies) to which this audit applies and indicate product type.*

Electrical equipment with type(s) of protection : i  d  e  m  n  t

Protective system

Safety, controlling or regulating device

**Audit Team Leader** : Mr. James Qian

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2	Introduction
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## **1 SUMMARY REPORT**

### **Summary of observations:**

The company is certified according to ISO 9001:2015, CHINA QUALITY MARK CERTIFICATION CENTRE. In addition the company is certified according to ISO/IEC 80079-34:2018 (ATEX-Directive and IECEX-System), Typs of protection are d, t; (TÜV Rheinland Industrie Service GmbH)  
The organization has established, documented, and implemented a QM system pursuant to DIN EN ISO 9001:2015 and ISO/IEC 80079-34:2018.

### **Nonconformities**

4

### **Audit Team Leader recommendations**

- QAR issued, indicating compliance with IECEX, recommending that IECEX Certificate of Conformity be issued/maintained\***
- QAR issued, indicating general compliance with IECEX, even if minor Non-conformances are raised, recommending that IECEX Certificate of Conformity be issued/maintained\*** following receipt of satisfactory documentary evidence supporting effective corrective action. Corrective action to be verified at next surveillance visit
- QAR issued, indicating Non-compliance with IECEX due to Major Non-conformances being raised, recommending that IECEX Certificate of Conformity be issued only after a satisfactory follow-up visit. For issued IECEX Certificates of Conformity, recommendation that they be maintained providing a follow up visit is conducted within 2 calendar months\***. Follow up visits are required to verify that corrective actions have been effectively documented and implemented.
- QAR issued, indicating NON-compliance with IECEX, due to major Non Conformances being raised such that non-complying product may be released to the market, recommending that IECEX Certificate of Conformity be refused/suspended** A further complete assessment, including site assessment to be conducted
- QAR issued, indicating NON-compliance with IECEX, recommending that IECEX Certification be refused/suspended** New applications are to be closed complete assessment is to be conducted. Where IECEX Certification has previously been granted, suspend or withdraw any IECEX Certificates associated with this assessment and inform the IECEX Secretary and other ACBs

### **Audit Team Leader:**



Mr. James Qian

### **IECEX Certification Body:**



Andreas Maschke

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## **2 INTRODUCTION**

**Manufacturer (auditee)** : Ningbo HOYEA Machinery Manufacture Co., Ltd.  
Zhoujia, Hengxi town, Yinzhou district, Ningbo, Zhejiang, P.R.  
China

**Scope of audit**

<b>Type A</b> initial assessment/reassessment of manufacturer <u>with</u> a certified QS	■
<b>Type B</b> initial assessment/reassessment of manufacturer <u>without</u> a certified QS	□
<b>Type C</b> surveillance of manufacturer <u>with</u> a certified QS*	□
<b>Type D</b> surveillance of manufacturer <u>without</u> a certified QS	□
<b>Type E</b> integrated assessment, reassessment or surveillance of manufacturer to include ISO 9001	□

**Audit criteria** :

IEC 80079-34, Potentially explosive atmospheres – Application of quality systems  
Certificate No. IECEX TUR 16.0029 X from TÜV Rheinland (IECEX-Scheme)  
Certificate No. TÜV 16 ATEX 7412 X from TÜV Rheinland (ATEX)  
Certificate No. 00118Q35695R4M/3302 from CQC (ISO 9001:2015)

**Product(s):** Explosion-proof Solenoid

**Date(s) and duration of audit** :

ATEX / IECEX, Repeat Audit on 2019-04-26 by TÜV Rheinland,  
Name of Audit: Mr. James Qian.  
Duration: 1 day

Latest audits:

Repeat audit ISO 9001:2015, 2018-06-06 to 2018-06-07, CQC, Zhou Aisheng, 2 day(s)

## **3 AUDIT DATA**

**Composition of audit team:**

Mr. James Qian  
TÜV Rheinland (Shanghai) Co., Ltd.  
No.177, Lane 777, West Guangzhong Road, Jingan District, Shanghai, 200072, P.R.CHINA

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**Interviewed representatives of manufacturer (auditee):**

Weng Zhidan, General Manager  
 Zhang Ce, R&D Deputy President  
 Xu Zhiwen, Ex Representative  
 Lu Xiaomei, Production  
 Lian Diping, Sales  
 Hu Weipei, Purchase

**Changes in the management system / Contract review**

No major changes have been made to the management system and the management system documentation since the last audit. The order details which form the basis of the audit (including number of employees, scope and sites) reflect the actual situation in the organization.  
 The description of the scope in the certificate appropriately reflects the scope of the management system. A corresponding printing request is attached.

**Reference documents used:**

Directive 2014/34/EU Annex IV / VII  
 IEC 80079-34 :2018  
 IEC 60079-0 : General requirements  
 IEC60079-1: Flameproof enclosures 'd'  
 IEC60079-31: Flameproof enclosure 't'

**Positive findings and opportunities for improvement**

No.	Unit/Department Site	Positive findings
1	Document	Most of the documents and records are made by paper type into electronic type, easier to manage.

The following recommendations and opportunities for improvement provided by the auditor are intended to contribute to the continuous improvement of the management system. They also serve to eliminate any weaknesses still existing in the organization, ensure management system effectiveness and prevent nonconformities.

No.	Unit/Department Site	Recommendations and opportunities for improvement
1	Warehouse	Warehouse shelves have no number, which is not easy to manage.

**4 DOCUMENT REVIEW and INDIVIDUAL ASSESSOR'S REPORT – Assessment of Implementation**

**Requirements 2014/34/EU / IECEX-System**

<b>Item</b>	<b>Audit result</b>
<b>4.4 Quality management system and its processes</b>	The quality management system ensures that the Ex products comply with the types described in the certificate and the technical documentation. The relevant parts of the ISO/IEC 80079-34 standard are fully applied.
<b>5.3 Organizational roles, responsibilities and authorities</b>	An Ex-Representative is named, who meets the following requirements: <ul style="list-style-type: none"> <li>• the effective co-ordination of activities with respect to Ex Products</li> <li>• liaison with the Notified Body responsible for issuing the ex-certificate with regard to any intended changes</li> <li>• liaison with the Notified Body responsible for quality management system with regard to intended updates of the system</li> <li>• the authorization of initial approval and changes to related drawings, where appropriate</li> <li>• the authorization of concessions</li> <li>• the accuracy of the ex-product information provided to the customer in sales information and installation instructions (which must include the specific conditions of use and scheduled restrictions)</li> <li>• the effective coordination of manufacturing processes of Ex products, including externally supplied products</li> </ul> <p>Quality manual Document index No. Q/NBHY G1001-2018 Version: A.03 Issue date: 2019-01-01</p>
<b>7.1.5 Monitoring and measuring resources</b>	The measuring equipment, used for Ex products, is calibrated and has a valid calibration sticker and certificate, examples: Pressure gauge  Monitoring & measurement device management procedure Document index No. Q/NBHY G2012-2015 Version: A.01 Issue date: 2015-06-01
<b>7.2 Competence</b>	All persons who are involved in the conformity process of the ex-products are trained and competent.  HR management procedure Document index No. Q/NBHY G2004-2015 Version: A.01 Issue date: 2015-06-01
<b>7.4 Communication</b>	Internal and external communication relating to Ex Products are controlled.
<b>7.5 Documented information</b>	All requirements and regulations for ensuring the conformity of the Ex products with their certificates and the associated technical documentation are regulated and managed in a systematic manner. Processes / procedures specify how changes are internally and externally managed (responsible for the Ex-Product and/or QM system). Ex-relevant technical documents are marked as follows: with 'Ex' marking A review of the validity of all Ex-related certificates, standards, directives, etc. is taking place annually.  Technology document management procedure Document index No. Q/NBHY G3301-2015

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Item	Audit result
	<p>Version: A.01 Issue date: 2015-06-01</p> <p>A minimum of 10 years retention time is required; beginning after the specific Ex Product (batch) has been placed on the market.</p> <p>Record control procedure Document index No. Q/NBHY G2002-2015 Version: A.01 Issue date: 2015-06-01</p>
<b>8.2 Requirements for products and services</b>	<p>It is evaluated whether specified customer requirements are compatible with the certificate. The Ex-Representative will be involved in any changes that affect the conformity of Ex-products.</p>
<b>8.3.6 Design and development changes</b>	<p>The Ex-Representative will be involved in any changes that affect the conformity of Ex-products.</p> <p>Engineering change control process Document index No. Q/NBHY G2009-2015 Version: A.01 Issue date: 2015-06-01</p>
<b>8.4 Control of externally provided processes, products and services</b>	<p>Suppliers of crucial parts (BoM) related to products with an EU Type Examination or Technical Report are selected after initial assessment and after that a periodic monitoring. For procured products that can influence the type of protection are specified verification measures for compliance in place.</p> <p>Supplier management procedure Document index No. Q/NBHY G2010-2015 Version: A.01 Issue date: 2015-06-01</p> <p>The following suppliers have influence the type of protection and are under periodic monitoring: Ningbo Aizhifu Sealing Technology Co., Ltd. For material-related suppliers, corresponding declarations of conformity or inspection certificates are available.</p> <p>Supplier management procedure Document index No. Q/NBHY G2010-2015 Version: A.01 Issue date: 2015-06-01</p>
<b>8.5 Production and service provision</b>	<p>Traceability and identification of the Ex-Product and their parts is during all stages of production and delivery are guaranteed. Traceability for the final product and its important parts are guaranteed. The Ex-Representative will be involved in any changes that could affect the conformity of Ex-Products. Routine tests are required for the following products: E-DTBBL-50FYC Production/assembly and final tests are carried out according to the specification. Example: Work/ test instruction inspection &amp; test management procedure An operating manual that has been prepared in accordance with the applicable standards and/or the statutory and regulatory requirements is enclosed with the Ex-product or is otherwise accessible for the customer (e.g. website)</p>

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Item	Audit result
	Production management process Document index No. Q/NBHY G2011-2015 Version: A.01 Issue date: 2015-06-01
<b>8.7 Control of nonconforming outputs</b>	If nonconforming products with potential hazards have already been shipped, customers and competent certification bodies will be informed in writing. Records of nonconforming products will be kept for at least 10 years.  Nonconforming control procedure Document index No. Q/NBHY G2016-2015 Version: A.01 Issue date: 2015-06-01
<b>9 Performance evaluation</b>	All aspects of Directive 2014/34/EU or IECEx-System are reviewed in internal audits annually.  Internal audit procedure Document index No. Q/NBHY G2013-2015 Version: A.01 Issue date: 2015-06-01  The management review of 2019-04-19 was carried out according to requirements and effectively and includes the effectiveness of quality management with regard to the Ex-Products. The Ex-Representative participated in the evaluation.  Management review procedure Document index No. Q/NBHY G2003-2015 Version: A.01 Issue date: 2015-06-01

Chapter of standard	4.1	4.2	4.3	4.4	5.1	5.2	5.3	6.1	6.2	6.3		
Rating *	1	1	1	3	1	1	1	1	1	1		
No. of nonconformity				1								
Chapter of standard	7.1	7.2	7.3	7.4	7.5	8.1	8.2	8.3	8.4	8.5	8.6	8.7
Rating *	1	1	1	1	1	1	1	1	1	3	1	3
No. of nonconformity										2,4		3
Chapter of standard	9.1	9.2	9.3	10.1	10.2	10.3						
Rating *	1	1	1	1	1	1						
No. of nonconformity												

\*Rating: 1 = conforming  
2 = not audited in this audit  
3 = failed/nonconformity (see nonconformity report)

**5 NONCONFORMITY REPORT**  
look at separate non-conformity report

**NCR No: 4**

**6 APPENDICES (optional)**  
additional assessor notes  
summary of audit trail (e.g. who? what? when? etc.)