ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attestation of Conformity

N8A 081068 0014 Rev. 00

Holder of Certificate: **Haier Medical and Laboratory Products Co., Ltd.**
Haier Industrial Park, Qingdao Economic Technology Development Zone
266510 Qingdao, Shandong
PEOPLE'S REPUBLIC OF CHINA

Product: **Safety cabinets (Biological Safety Cabinet)**

This Attestation of Conformity is issued on a voluntary basis according to the Low Voltage Directive 2014/35/EU relating to electrical equipment designed for use within certain voltage limits. It confirms that the listed equipment complies with the principal protection requirements of the directive and is based on the technical specifications applicable at the time of issuance. It refers only to the particular sample submitted for testing and certification. See also notes overleaf.

Test report no.: 64111170731601

Digitally signed by Jighili Tatiana
Date: 2021.07.23 19:10:52 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2018-07-31 (Bin Li)

After preparation of the necessary technical documentation as well as the EU declaration of conformity the required CE marking can be affixed on the product. The declaration of conformity is issued under the sole responsibility of the manufacturer. Other relevant EU-directives have to be observed.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

Attestation of Conformity

N8A 081068 0014 Rev. 00

Model(s): **HR900-IIA2, HR1200-IIA2, HR1500-IIA2, HR1200-IIA2-D, HR1200-IIA2-S**

Brand: **Haier**

Parameters:

Rated Voltage: 220-240V~
Rated Frequency: 50Hz
(HR900-IIA2, HR1200-IIA2, HR1500-IIA2);
50Hz/60Hz
(HR1200-IIA2-D, HR1200-IIA2-S)
Rated Power: 1500VA for HR900-IIA2, HR1200-IIA2;
1900VA for HR1500-IIA2;
1600VA for HR1200-IIA2-D, HR1200-A2II-S
Protection Class: Class I
Class of MSC: II

Tested according to:

EN 12469:2000
EN 61010-1:2010

After preparation of the necessary technical documentation as well as the EU declaration of conformity the required CE marking can be affixed on the product. The declaration of conformity is issued under the sole responsibility of the manufacturer. Other relevant EU-directives have to be observed.

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TÜV®

C E R T I F I C A T E

of Conformity

EC Council Directive 2014/30/EU

Electromagnetic Compatibility

TÜVRheinland®

Registration No.: AE 50459917 0001

Report No.: 50323937 001

Holder: Qingdao Haier Biomedical Co., Ltd.
Haier Industrial Park,
Economic Technology Development Zone,
Qingdao
P. R. China

Product: Refrigerator
(Pharmaceutical Refrigerator)

Identification: HYC-290 HYC-390 HYC-390F

Serial No.: n.a.
Remark: Refer to test report 50323937 001 for details.

Tested acc. to: EN 61326-1:2013

This certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical Report and documentation are at the Licence Holder's disposal. This is to certify that the tested sample is in conformity with all provisions of Annex I of Council Directive 2014/30/EU. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder of the certificate is authorized to use this certificate in connection with the EC declaration of conformity according to the a.m. Directive.

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle

Date 03.03.2020

Xinhua Lu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

CE The CE marking may only be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland (China) Ltd.
Member of TÜV Rheinland Group

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Qingdao Haier Biomedical Co., Ltd.

Date : 03.03.2020
Our ref. : ZX 01
Your ref.: P.M.

Haier Industrial Park,
Economic Technology Development
Zone,
Qingdao
P. R. China

Ref : AE Certificate of Conformity EMC

Type of Equipment : Pharmaceutical Refrigerator
Model Designation : See Certificate
Certificate No. : AE 50459917 0001
Report No. : 50323937 001

Dear Ladies and Gentlemen,

We herewith confirm that a sample of the above mentioned technical equipment has been tested and was found to be in accordance with the relevant requirements.

Enclosed please find your Certificate of Conformity.

We appreciate your kind support and would like to offer our assistance and continuous services in the future.

With kind regards,

Certification Body

Xinhua Lu

Enclosure

TÜV Rheinland (China) Ltd.
莱茵检测认证服务（中国）有限公司
Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
北京市朝阳区东三环中路乙10号
艾维克大厦707室
邮编：100022
Tel: (8610)6566 6660
Fax: (8610)6566 6667
e-mail: info@bj.chn.tuv.com
Internet: http://www.chn.tuv.com

C E R T I F I C A T E

of Conformity
EC Council Directive 2014/30/EU
Electromagnetic Compatibility

TÜVRheinland®

Registration No.: AE 50453377 0001

Report No.: 50320313 001

Holder:
Qingdao Haier Biomedical Co., Ltd.
Haier Industrial Park,
Economic Technology Development Zone,
Qingdao
P. R. China

Product:
Refrigerator
(Pharmaceutical Refrigerator)

Identification:
HYC-610

Serial No.: n.a.
Remark: Refer to test report 50320313 001 for details.

Tested acc. to:
EN 55014-1:2006+A1+A2
EN 55014-2:2015
EN IEC 61000-3-2:2019
EN 61000-3-3:2013
EN 55014-1:2017

This certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical Report and documentation are at the Licence Holder's disposal. This is to certify that the tested sample is in conformity with all provisions of Annex I of Council Directive 2014/30/EU. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder of the certificate is authorized to use this certificate in connection with the EC declaration of conformity according to the a.m. Directive.

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 16.12.2019

Xinhua Lu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

CE The CE marking may only be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland (China) Ltd.
Member of TÜV Rheinland Group

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Qingdao Haier Biomedical Co., Ltd.
Wang Xinxin
-
Haier Industrial Park,
Economic Technology Development
Zone,
Qingdao
P. R. China

Date : 16.12.2019
Our ref. : ZX 01
Your ref.: W.X.X.

Ref : AE Certificate of Conformity EMC

Type of Equipment : Pharmaceutical Refrigerator
Model Designation : See Certificate
Certificate No. : AE 50453377 0001
Report No. : 50320313 001

Dear Wang Xinxin,

We herewith confirm that a sample of the above mentioned technical equipment has been tested and was found to be in accordance with the relevant requirements.

Enclosed please find your Certificate of Conformity.

We appreciate your kind support and would like to offer our assistance and continuous services in the future.

With kind regards,

Certification Body

Xinhua Lu

Enclosure

TÜV Rheinland (China) Ltd.
莱茵检测认证服务（中国）有限公司
Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
北京市朝阳区东三环中路乙10号艾维克大厦707室
邮编：100022
Tel: (8610)6566 6660
Fax: (8610)6566 6667
e-mail: info@bj.chn.tuv.com
Internet: http://www.chn.tuv.com

认证证书

标准	**ISO 9001:2015**
证书登记号码	**01 100 2032721**
证书持有者：	Haier Biomedical 海尔生物医疗 **青岛海尔生物医疗股份有限公司** 统一社会信用代码：91370211780374731M 注册地址：中国山东省青岛经济技术开发区海尔工业园内 邮编：266510 经营地址：中国山东省青岛市高新区丰源路 280 号 邮编：266111
认证范围：	低温储存设备及其自动化系统、生物防护设备、干燥培养与孵育设备、灭菌消毒设备、样本分离设备的设计、制造和服务。生物医疗行业物联网整体解决方案的提供及软件的开发、咨询、实施和服务。
	证明完成了审核并满足了 ISO 9001:2015 标准的要求。
有效期：	证书有效期从 2021-07-03 至 2024-07-02。 此证书须经过符合要求的监督审核保持有效。 本证书信息可在国家认证认可监督管理委员会官方网站上查询 http://www.cnca.gov.cn

2021-07-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 2032721**

Certificate Holder:

Haier Biomedical
海尔生物医疗

Qingdao Haier Biomedical Co., Ltd.
Unified Social Credit Code: 91370211780374731M
Registration Address: Haier Industrial Park, Qingdao Economic & Technological Development Zone, Qingdao City, 266510 Shandong, P. R. China
Operation Address: No. 280, Fengyuan Road, High-tech Zone, Qingdao City, 266111 Shandong, P. R. China

Scope:

Design, Manufacture and Service on Low Temperature Storage Equipment and Relevant Automation System, Bio-protection Equipment, Dry Incubation Equipment, Steam Sterilization and Disinfection Equipment, Bio-sample Separation Equipment. Provision of Overall IoT Solutions and Development, Consulting, Implementation and Service of Software in Biomedical Industry.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2021-07-03 until 2024-07-02.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2021-07-03

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1809187-1

Organization: Qingdao Haier Biomedical Co., Ltd.
Haier Industrial Park, Economic
Technology Development Zone
Qingdao
266510 Shandong
P.R. China

Scope: Manufacture and Distribution of Refrigerators and Freezers for Medical Use, Pharmaceutical Refrigerators, Pharmaceutical Refrigerators and Freezers, Biological Safety Cabinets and Laminar Flow Cabinets

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 15070903 013

Effective date: 2020-09-22

Expiry date: 2023-07-27

Issue date: 2020-09-22

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1809187-1

Organization: Qingdao Haier Biomedical Co., Ltd.
Haier Industrial Park, Economic
Technology Development Zone
Qingdao
266510 Shandong
P.R. China

:

No.	Facility	Scope
/01	Qingdao Haier Biomedical Co., Ltd. Haier Industrial Park, Economic Technology Development Zone Qingdao 266510 Shandong P.R. China	Storage of Refrigerators and Freezers for Medical Use, Pharmaceutical Refrigerators, Pharmaceutical Refrigerators and Freezers, Biological Safety Cabinets and Laminar Flow Cabinets
/02	Qingdao Haier Biomedical Co., Ltd. Haier Industrial Park, No. 1 Haier Road, Qingdao, 266101 Shandong P.R. China	Administration of Refrigerators and Freezers for Medical Use, Pharmaceutical Refrigerators, Pharmaceutical Refrigerators and Freezers, Biological Safety Cabinets and Laminar Flow Cabinets
/03	Qingdao Haier Biomedical Co., Ltd. No.280 Fengyuan Road, High-tech Zone, Qingdao, 266111 Shandong P.R. China	Manufacture and Distribution of Refrigerators and Freezers for Medical Use, Pharmaceutical Refrigerators, Pharmaceutical Refrigerators and Freezers, Biological Safety Cabinets and Laminar Flow Cabinets

Report No.: 15070903 013

Effective date: 2020-09-22

Expiry date: 2023-07-27

Issue date: 2020-09-22

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

认证证书

标准	**ISO 45001:2018**
证书登记号码	**01 213 2032721**

证书持有者：

Haier Biomedical

海尔生物医疗

青岛海尔生物医疗股份有限公司

中国山东省青岛市高新区丰源路 280 号

邮编：266111

认证范围：

低温储存设备及其自动化系统、生物防护设备、干燥培养与孵育设备、灭菌消毒设备、样本分离设备的设计、制造和服务。生物医疗行业物联网整体解决方案的提供及软件的开发、咨询、实施和服务。

证明完成了审核并满足了 ISO 45001:2018 标准的要求。

有效期：

证书有效期从 2021-07-03 至 2024-07-02。

此证书须经过符合要求的监督审核保持有效。

2021-07-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Certificate

Standard **ISO 45001:2018**

Certificate Registr. No. **01 213 2032721**

Certificate Holder: Haier Biomedical 海尔生物医疗

Qingdao Haier Biomedical Co., Ltd.
No. 280, Fengyuan Road, High-tech Zone, Qingdao City, 266111
Shandong, P. R. China

Scope: Design, Manufacture and Service on Low Temperature Storage Equipment and Relevant Automation System, Bio-protection Equipment, Dry Incubation Equipment, Steam Sterilization and Disinfection Equipment, Bio-sample Separation Equipment. Provision of Overall IoT Solutions and Development, Consulting, Implementation and Service of Software in Biomedical Industry.

Proof has been furnished by means of an audit that the requirements of ISO 45001:2018 are met.

Validity: The certificate is valid from 2021-07-03 until 2024-07-02.
It remains valid subject to satisfactory surveillance audits.

2021-07-03

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