

EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Registration No.: DD 60149058 0001

Report No.: 15070903 009

Manufacturer: Qingdao Haier Biomedical Co., Ltd.

Haier Industrial Park, Economic Technology Development Zone

Qingdao

266510 Shandong

P.R. China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: DD 60139988 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date:

2020-06-16

Date:

2020-06-16

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

DD 60149058 0001

15070903 009

Manufacturer:

Report No.:

Qingdao Haier Biomedical Co., Ltd. Haier Industrial Park, Economic Technology Development Zone

Qinqdao

266510 Shandong

P.R. China

Products:

- Blood Bank Refrigerators
- (Ultra) Low Temperature Freezers for Medical Use

Site included:

Qingdao Haier Biomedical Co., Ltd. Haier Industrial Park, No. 1 Haier Road, 266101 Qingdao, P.R.China

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

Date: 2020-06-16

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Notified Body

TÜVRheinland

Fuxiu Sheng