

# EC Declaration of Conformity

*Manufacturer:*

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

*whose single Authorized Representative:*

Elscolab BV.  
Tolboomweg 10,3784 XC Terschuur, the  
Netherlands

We, the manufacturer, herewith declare that the products

(Ultra) Low Temperature Freezers for Medical Use

Type: DW-25L262, DW-25L92, DW-40L262, DW-40L278, DW-40L348, DW-40L508, DW-40L420F, DW-40L92, DW-40W100, DW-40W255, DW-40W380, DW-86L338, DW-86L338J, DW-86L388A, DW-86L388J, DW-86L486, DW-86L490J, DW-86L578J, DW-86L628(50Hz), DW-86L628(60Hz), DW-86L728D, DW-86L728J, DW-86L729, DW-86L828, DW-86L828J, DW-86L828W, DW-86L959, DW-86L959W, DW-86W100, DW-86W100J, DW-86W420, DW-86W420J, DW-30L278, DW-30L508, DW-30L420F, DW-86L578S, DW-86L578ST, DW-86L829BP, DW-86L829BPT, DW-86L959BP, DW-86L959BPT, DW-86L486E, DW-86L628E, DW-40L278(a), DW-40L348(a), DW-40L508(a), DW-40W100J, DW-40W255J, DW-40W380J, DW-60W138, DW-60W258, DW-60W388, DW-86L729BP, DW-86L729BPT, DW-86L579BP, DW-86L579BPT, DW-86L728S, DW-86L728ST, DW-30L818BP, DW-30L818BPT, DW-30L818, DW-30L1280F, DW-86L1280FT, DW-86L100J, DW-86L419, DW-86L579, DW-86L729, DW-86L829

UMDNS-Code: [15583]

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa by rule 2 according to Annex IX of the Directive 93/42/EEC. It bears the mark.

**CE 0197**

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body.

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2, 90431, Nürnberg, Germany**

Certificate No.: DD 60149058 0001

Issue date: 2020-06-16

Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective serial of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Qingdao Haier Biomedical Co., Ltd.

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

Qingdao 2020-10-19

Place, date

Head of Quality

Legally binding signature, Function

**EC Declaration of Conformity**  
**CE01-1**