EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

Development Zone, Qingdao P.R. China

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-86L388J, DW-86L388J, DW-86L486E, 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-86L728ST, DW-86L579BPT, 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-30L818BP, DW-30L818BPT, DW-30L1280F, DW-30L1280FT

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.

C € 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 60139988 0001 Issue date: 2019-07-08 Expiry date: 2024-05-27

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 2020-05-22

Place, date

EC Declaration of Conformity CE01-1

Liu Xueliang, Head of Qty

Legally binding signature, Function

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