

EC Declaration of Conformity

Manufacturer:

whose single Authorized

Representative:

Hangzhou Hua'an Medical & Health Instruments Co., Ltd. Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District ,Hangzhou, Zhejiang 310023 China	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg Germany
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We, the manufacturer, herewith declare that the products

Product name: Digital Thermometer

Type(s):

DT-01A, DT-01B DT-01D, DT-01E DT-01G	DT-11A, DT-11B DT-11D, DT-11E DT-11G,DT-11H	DT-02, DT-12	DT-101A, DT-111A DT-101B, DT-111B DT-111D,DT-111G	DT-K01A, DT-K11A, DT-K11B,DT-K11E DT-K101A, DT-K111A, DT-K111B,DT-K111D,	DT-Y111D
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UMDNS-Code: **[14-032]**

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

The medical device has been assigned to class IIa according to [Rule 10 of section III of Annex IX](#) of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to [Annex II\(excluding section 4\)](#) 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.: [60135526 0001](#)

Issue date: [22.02.2019](#)

Expiry date: [16.02.2024](#)

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

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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

Company: Hangzhou Hua'an Medical & Health Instruments Co., Ltd.

Address: Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District ,Hangzhou, Zhejiang 310023 China

Hangzhou China, [Feb. 25, 2019](#)


Mr. Zhang Hong, Manager