

# EC Declaration of Conformity

Manufacturer:

whose single Authorized

Representative:

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

**Product name: Digital Thermometer**

**Type(s): DT-K01A, DT-K101A, DT-K11B, DT-K111B,**

*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 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**

Registration No.: HD 60135526 0001

Report No.: 15066044 008

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following the procedure relating to the EC Declaration of Conformity set out in Annex II 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: Hanzhou Hua'an Medical & Health Instruments Co., Ltd.

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

Hangzhou, Zhejiang, China

Hangzhou China, June 22, 2021

Mr. Zhang Hong, General Manager

