

Hangzhou Hua'an	Version: <b>A</b>
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## EC Declaration of Conformity

*Manufacturer:*

*whose single Authorized Representative:*

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

**Product name: Infra-red Forehead Thermometers**

**Product code: FT-100B**

**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 Annex IX of the Directive 93/42/EEC. It bears the mark

**C E0197**

The product concerned has been designed and 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**

**Registration No.: HD 60135526 0001      Report No.: 15066044 008**

**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, Mar.16, 2020

Mr. Ji Bo, Manager

