

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

Product name: Infrared Ear Thermometer

Type(s): ET-100A, ET-100B, ET-100D, ET-100E,ET-100G,ET-100I,ET-100J

UMDNS-Code: [17-887]

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

杭州华安医疗保健用品有限公司
HANGZHOU HUA'AN MEDICAL & HEALTH INSTRUMENTS CO.,LTD