

EC Declaration of Conformity

Manufacturer:
Representative:

whose single Authorized

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

Prooduct name: Digital Thermometer

Manufacturer's model number	Cutomer's Brand Name	REF.
DT-01E	MEDEL THERMO	95128
DT-K111A	MEDEL FLEXO	95206

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 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: 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