

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60135526 0001

Report No.: 15066044 008

Manufacturer: Hangzhou Hua'an Medical &
Health Instruments Co., Ltd.
Building 2, 1# Fuzhu Nan RD
Wuchang Town, Yuhang District
310023 Hangzhou, Zhejiang
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60091996 0001

Expiry Date: 2024-02-16

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-02-22

Date: 2019-02-22



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

Manufacturer: Hangzhou Hua'an Medical &
Health Instruments Co., Ltd.
Building 2, 1# Fuzhu Nan RD
Wuchang Town, Yuhang District
310023 Hangzhou, Zhejiang
China

Products:

- Digital Thermometers
- Infra-red Ear Thermometers
- Digital Blood Pressure Monitors (Digital Sphygmomanometers)
- Infra-red Forehead Thermometers

Date: 2019-02-22



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

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



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

杭州华安医疗健康用品有限公司
HANGZHOU HUA'AN MEDICAL & HEALTH INSTRUMENTS CO., LTD

Mr. Zhang Hong, Manager

DIGITAL THERMOMETER °C - display

Code: 25559

Category: Digital thermometers

Unit of sale: box of 36 pcs.

Minimum order: 1

Type: Medical device

Class: II A

NSIS: 224155

CND: V03010102

EAN13: 8023279255591



Description: DIGITAL THERMOMETER °C - box - 30 seconds
Sold in a counter display of 36 pcs. (GB - IT)

Provide accurate and quick read-out. Safe and easy to use with clear and large display.

- display range 32.0°C- 42.9°C
- accuracy $\pm 0.1^{\circ}\text{C}$
- memory: last reading
- beeper function and auto shut-off
- plastic case
- multilanguage manual and box (GB, FR, IT, ES, PT, GR)

Works with battery LR/4I - 1.5V