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

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle
S. Liu

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.

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Doc. 1/1, Rev. 0

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

Notified Body

Date: 2019-02-22

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu