

EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Registration No.: DD 60091996 0001

Report No.: 15066044 001

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 60080443 0001

Expiry Date: 2019-02-16

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date:

2014-02-17

Date:

2014-02-17

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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Notified Body

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 Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.: Report No .:

DD 60091996 0001

15066044 001

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: 2014-02-17

