

EC Certificate

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

Registration No.: DD 60128509 0001

Report No .:

15058482 007

Manufacturer:

Wenzhou Bokang Instruments Co., Ltd. No. 1500 Haining Road

Haibin, Longwan 325024 Wenzhou

China

Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60084253 0001

Expiry Date:

2023-04-27

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:

2018-04-28

Date:

2018-04-16

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 Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

DD 60128509 0001

Report No.:

15058482 007

Manufacturer:

Wenzhou Bokang Instruments Co., Ltd. No. 1500 Haining Road Haibin, Longwan 325024 Wenzhou China

Products:

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- Electronic Sphygmomanometers
- Digital Thermometers
- Infrared Forehead Thermometers

Aspects of manufacture concerned with conformity of products with the metrological requirements:

- Aneroid Sphygmomanometers
- Mercury Sphygmomanometers restricted for Healthcare Use only



Date: 2018-04-16

