

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

TÜVRheinla

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



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

DD 60128509 0001

15058482 007

Manufacturer:

Report No.:

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

Haibin, Longwan 325024 Wenzhou

China

Products:

- 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

