EC Certificate

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

TÜVRheinland®

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

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

X. Ren

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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:

- 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

Notified Body
X. Ren

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle