



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)

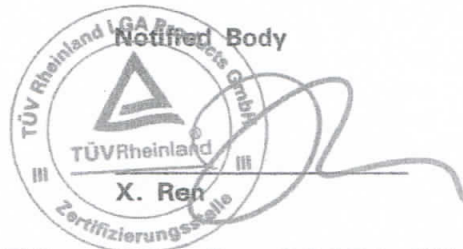
Replaces Approval, Registration No.: DD 60084253 0001

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.



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
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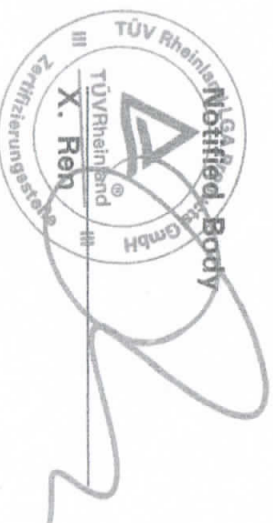
Products:

- 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



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of
Sphygmomanometers, Thermometers and Stethoscopes**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-04-28

Certificate Registration No.: SX 60128511 0001

An audit was performed. Report No.: 15058482 007

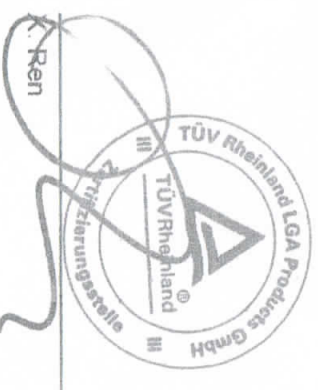
This Certificate is valid until: 2021-04-27

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-04-16



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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