# 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®

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# 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