EC Declaration of Conformity

Manufacturer:

Wenzhou Bokang Instruments Co., Ltd.

Add.No.1500 Haining Road Haibin, Longwan, 325024 Wenzhou, China

Tel:0086-577-86876969

whose single Authorized Representative:

Shanghai International Trading Corp. GmbH (Hamburg) Add:Eiffestrasse 80, 20537 Hamburg, Germany Tel: 0049-40-2513175 Fax: 0049-40-255726

We, the manufacturer, herewith declare that the products

Aneroid Sphygmomanometer

(BK2001,BK2001A,BK2002,BK2002A,BK2001-3001, BK2003,BK2004,BK2005,BK2006,BK2007, BK2008,BK2009,BK2099,BK2012,BK2013,BK2015,BK2015-2,BK2000,BK2020) *UMDNS-Code:* 16156; *GMDN-Code/Preferred Terms:* 16156

meet the provisions of Directive 93/42/EEC which apply to them. The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

€ € 0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.:DD 60128509 0001

Issue date: 2018-04-28

Expiry date: 2023-04-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

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



WENZOU, April 28,2018

Legally binding signature, Function

Place, date EC Declaration of Conformity BK-DC-03/D