

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Wenzhou Bokang Instruments Co., Ltd.

Shanghai International Holding Corp. GmbH (Europe)

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

Add:Eiffestrasse 80, 20537 Hamburg, Germany

Wenzhou, China

Tel: 0049-40-2513175

Tel:0086-577-86876969

Fax: 0049-40-255726

We, the manufacturer, herewith declare that the products

Electronic-sphygmomanometer

(BK6002, BK6022, BK6032)

UMDNS-Code: 16157; GMDN-Code/Preferred Terms: 45617, 47489

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 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: 1500 Haining Road Haibin, Longwan, 325024 Wenzhou, China

2018.3.25

Place, date

EC Declar:
BK-DC-01



Legally binding signature, Function