

EU Declaration of Conformity

MANUFACTURER (name and address): Wenzhou Bokang Instruments Co., Ltd.
No.1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026 Zhejiang Province, China

SRN: CN-MF-000021505

AUTHORIZED REPRESENTATIVE (name and address): Shanghai International Holding Corp. GmbH(Europe)
Eiffestraße, 80 20537 Hamburg, Germany

SRN: DE-AR-000000001

PRODUCTS:

Product Name	Product number / catalogue number	Basic UDI-DI	Description / intended purpose	Classification
Electronic Sphygmomanometer	BK1018	69310386ELC001C7	The device is used for measuring blood pressure and pulse rate from human upper arm.	Class IIa; Annex VIII, rule 10

CONFORMITY ASSESSMENT ROUTE: Annex IX excluding chapter II of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the provisions of the MDR (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer. Wenzhou Bokang Instruments Co., Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

STANDARDS APPLIED: EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-11:2015, EN ISO 81060-1:2012, IEC 80601-2-30:2018, ISO 81060-2:2018+A1:2020, EN 62366-1:2015+A1:2020, EN 60601-1-6: 2010+A2:2021, EN 62304:2006+A1:2015, EN ISO 14971:2019/A11:2021, ISO/TR 24971:2020, ISTA Procedure 2A: 2011.

NOTIFIED BODY: DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem
P.O. Box 5185
6802 ED Arnhem
The Netherlands
Notified body number: 0344

EC CERTIFICATE: No.: 6127621CE01, Valid: 1 July 2028

DESIGN EXAMINATION CERTIFICATE: N/A

START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Electronic Sphygmomanometer	BK6032	2023.07.31	2023.07.31

Place, Date of issue: Wenzhou, 2024-11-25

Date of expiration : 1 July 2028

SIGNATURE:



XIANG Youhua
General Manager
For and on behalf of Wenzhou
Bokang Instruments Co., Ltd.



WANG Xuemei
Regulatory Affairs Supervisor
For and on behalf of Wenzhou
Bokang Instruments Co., Ltd.