

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

PRODUCTS:

Product Name	Product number / catalogue number	Classification
CUFF	023+053.2, 022+053.2, 024+053.2 025+055.2, 028+058.2, 026+056.2, 027+057.2 0661, 0661L, 0661M	Class I; Annex VIII, rule 1

CONFORMITY ASSESSMENT ROUTE: Annex II + Annex III + Article 19 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 ISO 81060-1:2012, EN 62366-1:2015+A1:2020, EN ISO 14971:2019/A11:2021, ISO/TR 24971:2020, ASTM D 4169-16.

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

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.

