

EU Declaration of Conformity Medical Device Regulation 2017/745

For the following products:

NIBP Cuff and Accessories

(Product Name)

See attachment 1

(Model Designation)

We herewith declare that the device(s) that is covered by the present declaration is in conformity with Medical Device Regulation 2017/745. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Applicable harmonized standards are:

ISO 81060-1: 2007, EN 1041: 2008, EN ISO 15223-1: 2016, EN ISO 10993-5: 2009, EN ISO 10993-10: 2010, ISO 10993-1: 2018, EN ISO14971: 2012, EN ISO 13485: 2016

Conformity Assessment Route:

Medical Device Regulation 2017/745 annex II&III,IV



Classification: Class I, Rule 1

Basic UDI-DI: 69444140007SS

GMDN Code: 34978

European Authorized Representative:

Company Name: Shanghai International Holding Corp. GmbH (Europe)

Company Address: Eiffestrasse 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

Manufacturer:

Company Name: Shenzhen Med-link Electronics Tech Co.,Ltd.

Company Address: 4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi Community, Dalang Street, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA.

SRN: CN-MF-000011145

Signature:

Maolin Ye, General Manager

Name, position

Place, Date of Issue: Shenzhen City, 18th, Sept., 2023

Attachment 1 -- Model list

Device type	Model No.
NIBP Cuff	Y000A1, Y000A1-A04, Y000A1-A05, Y000A2, Y000N1, Y000N1-A05, Y000N2, Y000I1, Y000I1-A04, Y000I2, Y000C1, Y000C1-A04, Y000C1-A05, Y000C2, Y000S1, Y000S1-A04, Y000S2, Y000L1, Y000L1-A04, Y000L2, Y000T1, Y000T1-A04, Y000T2, Y101A1, Y103A2, Y001A1-A06, Y002A1-A06, Y000A1-A11, Y000L1-A11, Y000S1-A11, Y000A1-A118, Y003A1-A62, Y001A1-A06, Y000A2-A05, Y000C2-A05, Y000N2-A05, Y000L1-A05
	Y000RA1, Y000RA1-A04, Y000RA1-A05, Y000RA2, Y000RA2-A11, Y000RSA1, Y000RSA1-A04, Y000RSA1-A05, Y000RSA2, Y000RSA2-A11, Y000RC1, Y000RC1-A04, Y000RC1-A05, Y000RC2, Y000RC2-A11, Y000RAL1, Y000RAL1-A04, Y000RAL1-A05, Y000RAL2, Y000RAL2-A11, Y000RT1, Y000RT1-A04, Y000RT1-A05, Y000RT2, Y000RT2-A11, Y000RLA1, Y000RLA1-A04, Y000RLA1-A05, Y000RLA2, Y000RLA2-A11, Y000RI1-A04, Y102A1, Y104A2, Y000RTL1
Accessories	YA25A06-10, YA25A06-05, YA25A30-10, YA25A45-10, YA06A06-10, YA06A06-10H, YA06A06-12, YA10A01-12, YA18A01-10, YA07A08-10, YA06A106-10, YA100A03-10, YA47A48-10, YA48A48-12, YA24A10-08, YA24A10-12, YA24A109-12, YA24A10-24, YA24A16-12, YA24A12-12, YA23A10-12, YA23A12-12, YA40A12-12, YA23A16-08, YA10A102-24, YA10A12-08, YA22A12-12, YA22A10-12, YA22A16-08, YA28A11-08, YA29A06-08, YA12A116-12, YA47A06-10, YA28A30-08, YA14A06-10, YA53A16-08, YA55A06-06, YA06A12-10, YA03A49-A02A02, YA51A109-12, YA06A12-08, YA29A117-08
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Catalogue No.
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