

	EU Declaration of Conformity	Document No.	MDR-IBP
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	IBP cable	Version	1.0

EU Declaration of Conformity
TO REGULATION (EU) 2017/745 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

Manufacturer	Name: Shenzhen Medke Technology Co., Ltd. Address: 4/F, Bldg. A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist., Shenzhen, China 518126 SRN: noy yet applied
Authorised Representative	Name: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany SRN: DE-AR-000000001
Product Name	IBP cable
Trade Name	IBP cable
Model	Please refer to label
CND Code	Z12050385 ELETTROCARDIOGRAFI - MATERIALI SPECIFICI
Basic UDI-DI	Please refer to Attachment 2 – Basic UDI-DI in document MDR-ECG-CE-04 Device Description and Specification.
Intended Purpose	The IBP cable is intended to be used with monitors, connected with transducers to transfer signal.
Risk Class	Class I
Classification Rule	Rule 1 in Chapter III of Annex VIII of the Regulation (EU) 2017/745
Conformity Assessment Route	Annexes II and III of the Regulation (EU) 2017/745
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and the transposition into national law. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.	
Applied Standards	EN 62366-1:2015, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 14971:2012, EN ISO 15223-1:2016, AAMI EC53:2013
Place, Date of Issue	Shenzhen, Guangdong 2021-05-07
Signature:	  Name: Zuyin Xian Function: General Manager