EU Declaration of Conformity

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

深圳市曼克科技有限公司
受控文件

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	ECG Cable
Trade Name	ECG Cable
Model	Please refer to Appendix A attached in the last page of MDR-ECG-CE-04 Device Description and Specification.
CND Code	Z120503 ELECTROCARDIOGRAPHS
GMDN Code	37200 Cable, ECG
Basic UDI-DI	Please refer to Attachment Basic UDI-DI ECG
Device Photograph	Please refer to 1.9.1 Device photograph in MDR-ECG-CE-04 Device Description and Specification.
Intended Purpose	The ECG cable is intended to be used with ECG monitors. The lead wire is used to connect electrodes placed at appropriate sites on the patient to ECG monitors for general monitoring and/or diagnostic evaluation by healthcare professionals.
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 ISO13485:2016/AC:2018 MDR (EU) 2017/745 EN ISO14971:2019 IEC62366-1:2015 AAMI EC53:2013 MEDDEV.2.7.1 Rev4 EN ISO15223-1:2016 EN 1041:2008+A1:2013 ISO10993-1:2018 EN ISO10993-5:2009 EN ISO10993-10:2010
Place, Date of Issue	Shenzhen, Guangdong 2021-05-18
Signature:	Zuyin Xian Name: Zuyin Xian Function: General Manager