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: CN-MF-000019638
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
Basic UDI-DI	697101811ECGCABLEL6
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 Rev 4 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 2022-2-18
Signature:	Name: Zuxin Xian Function: General Manager

Digitally signed by Matei Vasile
Date: 2023.09.20 10:37:28 EEST
Reason: MoldSign Signature
Location: Moldova

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: CN-MF-000019638
Authorised Representative	Name: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany SRN: DE-AR-000000001
Product Name	NIBP air hose
Trade Name	NIBP air hose
Model	H series
CND Code	Z120401 General medicine instruments for diagnosis and monitoring
Basic UDI-DI	697101811NIBPairhoseJ7
Intended Purpose	The NIBP air hose connected with NIBP cuff, to display the patient's blood pressure signal at the monitors.
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 ISO 14971:2019 IEC 62366-1:2015 EN ISO81060-1:2012 MEDDEV.2.7.1Rev4 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 2022-02-18
Signature:	Name: Zuyin Xian Function: General Manager

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 085432 0005 Rev. 02

Holder of Certificate: **Shenzhen MedKe Technology Co., Ltd**
4/F, Bldg.A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist.
518126 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Medical Compressors and Nebulizers system, Medical accessories (including SpO2 sensors, Temperature probes, Patient cables and Lead wires, BP accessories and Infusors)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 085432 0005 Rev. 02

Report No.: GZ2211402

Valid from: 2023-01-17
Valid until: 2026-01-16

Date, 2023-01-05

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD
Product Service

Certificate

No. Q5 085432 0005 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Shenzhen MedKe Technology Co., Ltd
4/F, Bldg.A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist.,
518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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