

EU Declaration of Conformity Medical Device Regulation 2017/745

For the following products:

ECG Electrode

(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:

AASI/AAMI EC12-2000, 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

Conformity Assessment Route:

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



Classification: Class I, Rule 1

Basic UDI-DI: 69444140005SN

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.

Signature:

Maolin Ye, General Manager

Name, position

Place, Date of Issue: Shenzhen City, 13th May., 2021

Attachment 1 -- Model list

Model NO.
V0014F, V0014-D0845A-N, V0014-D0845A, V0014D, V0014C-RT, V0014CP, V0014C-I, V0014-C0405I, V0014-C0405A, V0014-C0403I, V0014-C0403A, V0014-C0245I, V0014-C0245A, V0014-C0243I, V0014-C0243A, V0014C, V0014B-RT, V0014B, V0014A-RT, V0014AP, V0014A-C0234I, V0014A, V0015-C0845A, V0015-C0845, V0015-C0603A