

EU Declaration of Conformity Medical Device Regulation 2017/745

For the following products:

EEG 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:

ANSI/AAMI EC12-2000(R2020), EN ISO 20417:2021, ISO 20417:2021, EN ISO 15223-1:2021, ISO 15223-1:2021, EN ISO 10993-1:2025, ISO 10993-1:2025, EN ISO 10993-5:2009, ISO 10993-5:2009, EN ISO 10993-10:2010, ISO 10993-10:2010, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, ISO 14971:2019

Conformity Assessment Route:

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



Classification: Class I, Rule 1

Basic UDI-DI: 69444140003SJ

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: Zone A of 1st and 2nd Floor, and 3rd Floor, Building A, No. 7, Tongsheng Industrial Park Road, Shanghenglang 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, 11st, Aug., 2026

Attachment 1 -- Model list

Model No.				
B112-P-BLA-60	B134-N-BLA-60	B134-N-BLK-60	B134-N-GRN-60	B134-N-RED-60
B134-P-BLA-60	B134-P-BLU-60	B134-P-BRN-60	B134-P-GRN-60	B134-P-RED-60
B134-P-WHE-60	B134-T-BLA-60	B134-T-GRN-60	B134-T-RED-60	B143-DP-10-60
B143-N-BLA-60	B143-N-BLU	B143-N-BLU-60	B143-N-BRO	B143-N-BRO-60
B143-N-GRN-60	B143-N-ORA	B143-N-ORA-60	B143-N-PUR	B143-N-PUR-60
B143-N-RED	B143-N-RED-60	B143-N-WHE-60	B143-N-YEL	B143-N-YEL-60
B143-P-05-30	B143-P-10-120	B143-P-10-48	B143-P-10-72	B143-P-10-96
B143-P-BLA-30	B143-P-BLA-39	B143-P-BLA-60	B143-P-BLU-60	B143-P-BRN-60
B143-P-GRN-30	B143-P-GRN-60	B143-P-GRY-30	B143-P-GRY-60	B143-P-ORA-60
B143-P-RED-30	B143-P-RED-60	B143-P-VIO-60	B143-P-WHE-60	B143-P-YEL-60
B143-T-BLA-60	B143-T-BLA-60-N	B143-T-GRN-60	B143-T-RED-60	B708-P-BLA-45
B143-DP-10-40	B143-DP-10-80	B143-DP10-100	B143-S-10-72	B143-S-10-120
B143-P-14-30	B143-DS-10-60	B143-DS-10-72	B143-DS-10-120	B143-P-10-60
Catalogue No.				
OEM-B3376A				