

EU Declaration of Conformity

Medical Device Regulation 2017/745

For the following products:

Disposable Non-invasive EEG Sensor

(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 10993-1:2020, ISO 10993-1:2018, 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: 69444140004SL

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*

Maolin Ye, General Manager

Name, position

Place, Date of Issue: Shenzhen City, 5th Jun., 2025

Attachment 1 -- Model list

Model No.				
Disposable Noninvasive EEG Sensor:				
B-BIS-6A	B-BIS-6A-01	B-BIS-6A-02	B-BIS-6A-03	B-BIS-5A
B-BIS-5A-01	B-BIS-4A	B-BIS-4P	B-BIS-4P-01	B-BIS-3A
B-BIS-4A-01	B-BIS-3A-01	B-BIS-3A-02	B-BIS-3A-03	B-BIS-3AL
B-BIS-3AL-01	B-BIS-3AR	B-BIS-3AR-01	B-BIS-3A-04	
Reusable Noninvasive EEG Sensor cable:				
B0052A	B0051A	B0050I	B0050A	B143-P-10-60
B0061A	B0067I			
Catalogue No.				
OBM-99030309-01	9902040901	9902040502	9902060901	9903030901
OEM-B3681A	OEM-B3998A	OEM-B3327D	OEM-B3327C	OEM-B3280A
OEM-B1304A	OEM-B3327B	OEM-3852B	OEM-B1304B	OEM-B3327A
OEM-3852A	B0054A	9902040904	9902040504	9902060902
OBM-B0287A	OEM-B1591A	6902040901	6902040501	