DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex IV of Regulation (EU) 2017/745

Applicable Standards
EN ISO 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
IEC 62366-1：2015

Remark
The declaration of conformity is valid in connection with the release technical document MK/MDR -01. All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Medker Medical Electronic Tech (Shenzhen) Co., Ltd.
Address: 501, Building A, Yeming Mould Industrial Park, No. 19 Baoshan Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen, Guangdong, China
SRN: CN-MF-000002911

Product Information

Name : Disposable EEG Sensor
Model: MK-01，MK-02，MK-03，MK-04
Basic UDI-DI :
6974452550007AP 6974452550028AX 6974452550035AU
6974452550021AH 6974452550011AE 6974452550042AR
6974452550045AX 6974452550004AH 6974452550059BA
6974452550069BD 6974452550073B4 6974452550066B7
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 2024.01.19

Position: GM Place: Guangdong/China