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 II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
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

Product Information

Name : Disposable EEG sensor
Disposable Bispectral Index Sensor
Model : MK-01 ; MK-02 ; MK-03 ; MK-04 ; MK-C-017
GMDN : 36366
Basic UDI-DI :
6974452550007AP 6974452550028AX 6974452550035AU
6974452550021AH 6974452550011AE 6974452550042AR
6974452550045AX 6974452550004AH 6974452550059BA
6974452550069BD 6974452550073B4 6974452550066B7
6974452550090B4 6974452550134AX
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. All supporting documentations are retained under the premises of the manufacturer.Medker is exclusively responsible for the declaration of conformity. Our products are Non-Sterile products.

Signature: Date: 2022. 11. 23

Position: GM Place: Shenzhen/China