DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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SRN: NL-AR-000000247

Manufacturer

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

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12101080 -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.

Product Information

Name: Disposable EEG Sensor
Model: MK-01、MK-02、MK-03、MK-04、MK-06、MK-08
EMDN: Z12101080
Basic UDI-DI: 697445255EEGIMB
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: 2024.08.05

Position: GM Place: Guangdong/China