



DECLARATION OF CONFORMITY

Regarding UK Medical Devices Regulations 2002

Manufacturer: 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

UK Responsible Person: SUNGO Certification Company Limited

Address: 3rd floor, 70 Gracechurch Street, London. EC3V 0HR

Product Name: Disposable EEG SensorAdult

Specification: MK-01,MK-02,MK-03,MK-04

GMDN: 11440

Classification: Class I

**Conformity Assessment
Procedure:** Rule 1, Annex IX, Directive 93/42, Part II of the UK MDR
2002

We herewith declare that the above-mentioned products meet the requirements of UK
Medical Devices Regulations 2002 and the following standards.

BS EN ISO 20417:2021 BS EN ISO 14971:2019 BS EN ISO 15223-1:2021
BS EN ISO 10993-5:2009 BS EN ISO 10993-1: 2020 BS EN ISO 10993-10: 2013

Signature: 

Position: GM

Date: 2024.1.3

Place: Guangdong/ China

The declaration of conformity is valid in connection with the release technical document UKCA-MK-TCF001.

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.