



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: 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-C020501-01.

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: SHENZHEN YKD TECHNOLOGY CO.,LTD.

Address: 6F, Building 6. Huaxinruiming Industrial Area, Langrong RD,Xinwei Village, Dalang Community, Dalang Street, Longhua, Shenzhen, China.

SRN: CN-MF-000017263

Product Information

Name: ECG ELECTRODES

Model:CKC001A1(CKC011B),

CKC001A2(CKC013E),

CKC001B1(CKC012,CKC012B),

CKC001B2(CKC014C),

CKC001C1(CKC011,CKC005,CKC005B,CKC009,CKC011D),

CKC001C2(CKC007,CKC013B)

EMDN: C020501

Basic UDI-DI: 697531983EE01KV

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: 2023.11.27

Position: GM

Place: Shenzhen/China