



# 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、CKC001A2、CKC001B1、CKC001B2、CKC001C1、CKC001C2

**EMDN:** C020501

**Basic UDI-DI:** /

**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

