



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Cert GmbH,  
Harffstr.47,40591 Düsseldorf, Germany  
SRN:DE-AR-000010869

## 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 ISO20417:2021  
ISO 10993-1:2018  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-YX-01/02/03/04.*

*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:YANCHENG TIANRUN MEDICAL INSTRUMENT FACTORY.

Address:4th floor, building 2-b-4, yancheng small and medium enterprises (venture) park, century avenue, yandu district, yancheng city

## Product Information

Name : ECG Electrodes、TENS electrodes、Medical Ultrasound Gel、ECG Conductive Gel

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: Xu Shu Lan Date:2021-08-04

Position: G.M.Place:YanCheng

