



**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-01/03/03/04

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 HUI SHENG 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