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 Ultrasoud 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 productsmeet 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

YANCHENG TIANRUN MEDICAL INSTRUMENT FACTORY 盐城市天润医疗器材