



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: SUNGO Europe B.V.

Address: 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: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
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-YIZHENG -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: JIANGSU YIZHENG CAREPRO MEDICAL INSTRUMENTS CO.,LTD.

Address: No. 3 Jingxiu Road, Yizheng Economic Development Zone, Jiangsu

SRN: CN-MF-000009036

Product Information

Name: Tape

Model: (0.5-20)cm x (1-35) m

GMDN: 16866

Basic UDI-DI: 69700292700000000000002W7

Classification: Class I

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: *David Shi* Date: 2022.11.22

Position: GM

Place: JiangSu

