

# 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: 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-DST-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: ANJI SUNLIGHT MEDICAL PRODUCTS CO.,  
LTD.

Address: No.499, North Raocheng Road, Dipu  
Street, Anji, Zhejiang Province, PEOPLE'S  
REPUBLIC OF CHINA

## Product Information

Name: Elastic Bandage

Model : 5CMX4.5M, 7.5CMX4.5M, 10CMX4.5M,  
15CMX4.5M, 6CMX4M, 8CMX4M, 10CMX4M,  
12CMX4M, 15CMX4M

Other sizes as per customer requirements.

GMDN: 13369 EMDN: M030401


Basic UDI-DI: 69524711EBA000026G

SRN: CN-MF-000014577

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: 2023.06.15

Position: GM

Place: Anji /China

