DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: ANJI SUNLIGHT MEDICAL PRODUCTS CO., LTD.
Address: No.499, North Raocheng Road, Dipu Street, Anji, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

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-PB-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is issued exclusively under the sole responsibility of the manufacturer.

Product Information

Name：Plaster of Paris Bandage
Model ： 5CMX2.7M, 7.5CMX2.7M, 10CMX2.7M, 12.5CMX2.7M, 15CMX2.7M, 20CMX2.7M, 5CMX3M, 7.5CMX3M, 10CMX3M, 12.5CMX3M, 15CMX3M, 20CMX3M, 6CMX3M, 8CMX3M, 12CMX3M
Other sizes as per customer requirements.
GMDN： 10284
Basic UDI-DI： /
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.

Digitally signed by Morozov Maria
Date: 2023.07.21 12:37:04 EEST
Reason: MoldSign Signature
Location: Moldova

Signature: Date: 2021.7.8

Position: GM Place: Anji/China