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

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 11199-2:2005

Remark
The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF01.
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: Jiangyin Huashi Medical Equipment Co., Ltd
Address: No.589, Hualu Road, Huashi Town, Jiangyin City, Jiangsu, China
SRN: CN-MF-000008896

Product Information

Name: Rollator
Model: HS8 (Dolomite Brass)
GMDN: 38702
Basic UDI-DI: 69731703270087H
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: 2022.1.28.

Position:GM Place: Jiangsu/China