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 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 11199-1: 1999

Remark
The declaration of conformity is valid in connection with the release technical document CE/MDR-DAW-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: Jinhua Huge Industrial Co., Ltd.
Address: 1st Floor,Unit 2,Building 2,Nanshi Community,Sanjiang Street,Wucheng District, Jinhua City, Zhejiang Province

Product Information

Name: ROLLATOR
Model: 381, 381L, 461L, 481L, 462L, 969LH, 463L, 483L, 484L, 485L, 465, 465L, 485W, 486L, 487, 5000, 968, 965, 966, 914, 5023, 5025, 5029
GMDN: 37951
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.

Signature:

Date: 9.9.2021

Position: GM

Place: Zhejiang/China