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, NL
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 11199-2: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y120612-01.

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: JIAXING XINYI MEDICAL EQUIPMENT CO., LTD

Address: No.100 Zhijiang Rd, Economic Development Zone,314100 Jiashan, Zhejiang, China

Product Information

Name: ROLLATOR

Model: XY801, XY802, XY803, XY883, XY853, XY855, XY884, XY893

Intend use: The rollator is intended to be used for people who are experiencing generalized weakness, difficulty with balance, a lower extremity injury or surgery that need additional support to maintain balance and stability while walking outdoors, or used for rehabilitation.

EMDN: Y120612

Basic UDI-DI: 697308277XY85RL

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: 2023-05-05

嘉兴信益医疗器材有限公司
JIAXING XINYI MEDICAL EQUIPMENT CO.,LTD.

Position: GM Place: Jiaxing /China