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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 11199-2:2005

Remark

The declaration of conformity is valid in connection with the release technical document [illegible] 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: ZHENJIANG RAPID REHAB & INSTRUMENT CO., LTD.
Address: NO.35 HUANCHENG SOUTH ROAD, PICHENG, DANBEI TOWN, DANYANG CITY, ZHENJIANG, JIANGSU, CHINA

Product Information

Name: Rollator
Model: See Annex
GMDN: See Annex
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: Wilson Chen Date: 4th Aug. 2021

Name: Wilson Chen Place: Zhenjiang / China

Position: GM

ZHENJIANG RAPID REHAB & INSTRUMENT CO., LTD. 镇江瑞德特医器械有限公司 3211817815939