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 10993-10: 2013
ISO 11199-2:2005
ISO 13485:2016 / ISO 9001: 2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-ASK-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: Foshan Oscar Medical Instrument Co., Ltd
Address: No.2, (Workshop C), Nanhai National Eco-industrial Demonstration Park, Danzao Town, Nanhai District, Foshan City, Guangdong Province, China
SRN: CN-MF-000007958

Product Information

Name: Rollator
Model: TRA01, TRA02, TRA02C, TRA03, TRA04, TRA08, TRA11, TRA14, TRA18, TRA21, TRA32M, TRA34, TRA22, TRA25, TRB01
GMDN: 38702
Basic UDI-DI: 697424257Rollator8P
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: 2021-6-24

Position: GM Place: Foshan/China