DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

Importer

Name: MultiMotion B.V.

Address: Weezenhof 6158, 6536 AM Nijmegen, The Netherlands

EU Representative

Name: SUNGO Europe B.V.

Address: Fascinatio Boulevard522,Unit 1.7,2909VA Capelle aan den IJssel,TheNetherlands

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

Item Numbers: 10050016 ; 10050017; 10050007 ; 10050008; 10050009 ; 10050010 ; 10050018 ; 10050015; 10050011 ; 10050012; 10050014; 10050013; MMEWR; TSA10

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: Louise Luo Date: 05/12/23

Position: Sales Manager Place: Foshan/China