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: 2023
EN ISO 10993-23:2021
EN 12183:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122103-01.

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: A & I Industries Ltd Shunde Foshan
Address: Lian Du Industry Park, Le Liu Town, Shun De District, Fo Shan City, Guangdong, China
SRN: CN-MF-000038647

Product Information

Name: Manual Wheelchair
Model: 3001, 3002, 218-23, 218 - 23 WHD, 118-23 118-23 Plus, 218-24, 108-23, Primeo, Primeo Plus 348-23, 318-23, Relax Comfort, 358-23, 228-24 J 538-23, 538-23 HEMI, 538-23 COMEORT
EMDN: Y122103
Basic UDI-DI: / 697786880MwheelchairT8
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: 2023.8.30

INDUSTRIES LTD SHUNDE FOSHAN 佛山市顺德区安美工业有限公司

Position: GM

Place: Guangdong /China