

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 20417:2021 EN ISO 15223-1: 2016 ISO 10993-1: 2018 EN ISO 10993-5: 2009 EN ISO 10993-10: 2013

EN 12183:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-Vans-TCF003.

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.

Excel Mobility Manufacturing Corporation Limited

Rm 1907, 19/F, Dominion Centre
43-59 Queen's Road East
Wan Chai, Hong Kong
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www.excel-mobility.com

Manufacturer

Name: Excel Mobility Manufacturing Corporation Ltd. Address: Rm 1907, 19/F., Dominion Centre, 43-59

Queen's Road East, Wan Chai, Hong Kong

Product Information

Name: Manual wheelchair

Model: see attachment

GMDN: 41631

Basic UDI-DI: 489711989002MJ

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: 2021.8.25

Position:GM

Place: Hong Kong

Annex

Product Name	Model	GMDN
Manual wheelchair	Excel G-Lite	41631
Manual wheelchair	Excel G-lite+	41631
Manual wheelchair	Excel G-lite+ Dynamique	41631
Manual wheelchair	Excel G-Lite+ Dynamique Recline	41631
Manual wheelchair	Excel G-Lite Pro	41631
Manual wheelchair	Excel Glide Pro	41631
Manual wheelchair	Excel G-Logic	41631
Manual wheelchair	Excel G-Explorer	41631
Manual wheelchair	Travixx Comfort Lite	41631
Manual wheelchair	Excel G4 Modular	41631
Manual wheelchair	Excel G5 Modular	41631
Manual wheelchair	Excel G5 Modular Kids	41631
Manual wheelchair	Excel G5 Modular Junior	41631
Manual wheelchair	Excel G5 Modular Plus	41631
Manual wheelchair	Excel G5 Modular Comfort	41631
Manual wheelchair	Excel G5 Modular Hemi	41631
Manual wheelchair	Excel G-Modular	41631
Manual wheelchair	Excel G-Modular Hemi	41631
Manual wheelchair	Excel G-Modular Comfort	41631
Manual wheelchair	Excel G-Neos	41631
Manual wheelchair	Excel G-Neos+	41631
Manual wheelchair	Excel G-Eco	41631

Annex

Product Name	Model	GMDN
Manual wheelchair	Excel G-Evolution	41631
Manual wheelchair	Excel G-Lightweight	41631
Manual wheelchair	Excel G3 Paediatric	41631
Manual wheelchair	Excel G-Nexx	41631
Manual wheelchair	Excel G-Basic	41631
Manual wheelchair	Excel G-Transit	41631
Manual wheelchair	Excel G-Entry	41631
Manual wheelchair	2GOability Access	41631
Manual wheelchair	Excel Access	41631
Manual wheelchair	Excel G-Lightweight	41631
Manual wheelchair	Excel G-Lightweight+	41631
Manual wheelchair	Excel G-Ligthweight Start	41631
Manual wheelchair	Excel G-Ligthweight+ 2	41631
Manual wheelchair	Excel Curve	41631

Signature:

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