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: 2013
EN 60601-1-2:2015/A1:2021
EN 60601-1:2006/A2: 2021
EN 12184: 2014

Remark
The declaration of conformity is valid in connection with the relevant technical document CE/MDR-Y122127-01.
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 SOWELL MEDICAL TECHNOLOGY CO., LTD.
Address: No. 13, Area C1, Dongjiao Nanhe Industrial Avenue, Dantou Town, Nanhai District, Foshan City, China
SRN:

Product Information

Name: Electric wheelchair
Model: SP-5001L, SP-5003L, SP-5003L, SP-5004L, SP-5005L
EMDN: Y122127
GMDN: 40540
Basic UDI-DI: /
Classification: Class I, According to Rule 13, 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: 2023.2.23

Position: GM Place: Foshan/China

USUNG

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Rijksoverheid Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Fascinatio Boulevard 522 (Unit 1.7)
2909 VA Capelle aan den IJssel

Formulier

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6464

https://loketmedischehulpmiddelen.nl

Onderwerpen vrije
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-[illegible]

Bijlagen

Uw aanvraag
24 februari 2023

Correspondentie uitsluitend richten aan het rechtspersoon met vermelding van de datum en het kenmerk van deze brief

Datum: 27 maart 2023
Betreft: notificatie medische hulpmiddelen klasse I

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 24 februari 2023 van de notificatie van de medische hulpmiddelen klasse I, die door Foshan Sigood Medical Technology Co., Ltd., met Europees gemachtigde SUNGO Europe B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
De producten zijn onder vermeld kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over een of meer van deze producten het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Cane&Crutch
(geen merknaam) (NL-CA002-2023-75159)
Electric wheelchair
(geen merknaam) (NL-CA002-2023-75157)
Manual wheelchair
(geen merknaam) (NL-CA002-2023-75156)
Transfer chair
(geen merknaam) (NL-CA002-2023-75158)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw producten overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

[1] D.g.v. art. 29 MDR.
[2] D.g.v. art. 31 MDR.

CONCEPT

FDA

Fiscal Year 2025

This is a notice to the establishment whose Facility Registration and Device Listing have been done within the Fiscal Year 2025.

Establishment information

Name: ZHEJIANG HFIZER MEDICAL EQUIPMENT CO.,LTD

Address: Yunliu Road, Baiyun Industrial Functional Zone, Jiangnan Street, Yongkang City, Zhejiang, 321300, CHINA

Inquiry Website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Facility Registration and Device Listing Information

Owner/Operator Number: 10091056			
Registration Number: 3031595780			
Listing No.	Product Code	Proper Name(s)	Registration Role
D538809	ITI (K240673)	Electric wheelchair	Manufacturer, Foreign Exporter
D551090	ITI (K242136)	Electric wheelchair (C001)	
D552985	ITI	Walker	

Reg

Health Canada / Santé Canada

Company ID / ID de l'entreprise: 192838

Licence Number 32864 Numéro de la licence

Medical Device Establishment Licence

Licence d'établissement pour les instruments médicaux

SHENZHEN WEIXING MEDICAL TECHNOLOGY CO., LTD.

BUILDING 1, HENGDA METROPOLITAN PLAZA NO. 15 HUANCHENG SOUTH ROAD, ROOM 2303
SHENZHEN, GUANGDONG
CHINA, 518129

This licence is issued in accordance with the *Medical Devices Regulations* of the *Food and Drugs Act* for the following activities:

Cette licence est délivrée conformément à la *Loi sur les aliments et drogues*, *règlement sur les instruments médicaux* pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	No / Non	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

Attestation made: **Attestations faites:**

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre des procédures écrites concernant:
- Distribution records	Yes / Oui	- les registres de distribution
- Complaint handling	Yes / Oui	- le traitement des plaintes
- Recalls	Yes / Oui	- les rappels
- Incident reporting	No / Non	- les rapports d'incidents
- Serious risk of injury to human health	No / Non	- les risques graves de préjudice à la santé humaine
- Servicing	No / Non	- l'entretien
- Corrective action	No / Non	- les mesures correctives
- Installation	No / Non	- l'installation
- Handling, storage, delivery	No / Non	- la manutention, le stockage et la livraison

Issue Date / Date de délivrance: Nov 24, 2025

Minister of Health / Ministre de la santé	Countersigned: Manager, Medical Devices Compliance Program or delegated authority Contresigné par: Gestionnaire, Programme de la conformité des matériels médicaux ou autorité délégué Marie-Odile M. Guerra

Site listing begins on the next page *Liste des sites commence à la page suivante*

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.
Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Sungo Australia Pty Ltd

for approval to supply

Sungo Australia Pty Ltd - Wheelchair, attendant/occupant, electric drive/steer, non-collapsible

ARTG Identifier	515192
ARTG Start Date	10/10/2025
Product Category	Medical Device Included Class 1
GMDN	41875
GMDN Term	Wheelchair, attendant/occupant, electric drive/steer, non-collapsible
Intended Purpose	An electric wheelchair is a power-driven mobility aid designed to help users with limited mobility improve their quality of life, featuring various functions and wide applications.

Manufacturer Details	Address	Certificate number(s)
Shenzhen Weibing Medical Technology Co Ltd	Room 2303 Building 1 Hengda Metropolitan Plaza No 15 Huancheng South Road Bantian Longgang , Shenzhen , China	

ARTG Standard Conditions

The above Medical Device included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Wheelchair, attendant/occupant, electric drive/steer, non-collapsible

Product Specific Conditions

No specific conditions have been recorded against this entry.

UK CA

DECLARATION OF CONFORMITY

Regarding UK Medical Devices Regulations 2002

UK Responsible Person

Name: SUNGO Certification Company Limited
Address: 3rd floor, 70 Gracechurch Street, London, EC3V 0HR

MHRA REGISTRATION REF NUMBER: 0000009302

Manufacturer

Name: Shenzhen Weixing Medical Technology Co., Ltd.
Address: Room 2303, Building 1, Hengda Metropolitan Plaza, No. 16 Huancheng South Road, Ranlan, Longgang, Shenzhen,518129,China

Conformity Assessment

Annex VII, Part II of the UK MDR 2002(SI 2002 No 618, as amended)

Product Information

Name: Electric Wheelchair

Model: See annex

Applicable Standards

BS EN ISO 14971:2019+A11:2021
BS EN ISO 15223-1:2021
BS EN ISO 20417:2021
BS EN ISO 10993-1:2020
BS EN ISO 10993-5:2009+A11:2025
BS EN ISO 10993-10:2023
BS EN ISO 10993-23:2021
BS EN 12184:2022
BS EN 60601-1:2006+A13:2024
BS EN 60601-1-2:2015+A1:2021
BS EN 62366-1:2015/A1:2020
BS ISO 7176-31:2023

Classification:

Class I, According to Rule 12, Annex IX, Directive 93/42,Part II of the UK MDR 2002(SI 2002 No 618, as amended)

Remark

The declaration of conformity is valid in connection with the release technical document UKCA-TCF-001.
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.

Declaration

We hereby declare, that the above-mentioned products meet the provisions of The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) and the standards.

Name Juan Wang Position General Manager

Signature Juan Wang Date 2025-10-27 Place Guangdong/China

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L5138

UN38.3 检测报告
UN38.3 Test Report

样品名称:	锂离子电池
Sample name:	Li-ion Battery Pack
样品型号: Sample model:	Li-ion-12Ah
委托单位:	深圳市加瑞网络服务有限公司
Applicant:	Shenzhen Jiarui Network Service Co., Ltd

深圳天溯计量检测股份有限公司
Shenzhen Tiansu Calibration and Testing Co., Ltd.

Address: No.2, Jinlong Avenue, Longgang District, Shenzhen, Guangdong, China
Web: www.tiansu.org E-mail: tsjc@tiansu.org Tel: 0755-89457984