



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 1041:2008+A1:2013
EN ISO 15223-1: 2016

Remark

*The declaration of conformity is valid in connection with the release technical document **MDR-DY-TCF001**.*

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: GUANGDONG DAYANG MEDICAL TECHNOLOGY CO., LTD.
Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA.

Product Information

Name: manual wheelchair
Model: See Annex
GMDN: See Annex
Basic UDI-DI: -
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:

2021.2.25

Name: Huang Zehui Place: Foshan / China

Position: GM

Annex

Product Name	Model	GMDN	Basic UDI-DI
manual wheelchair	DY01201LQ, DY01700LQ	46137 - Multi-terrain sports wheelchair, attendant/occupant-driven	-
manual wheelchair	DY01958LBCJ, DY01959LB, DY01953LQ, DY01953LCQ, DY01903LB, DY01903LABQ, DY01954LGC, DY01950LBQ, DY01955LB, DY01973LAH, DY01980LA-46, DY01980LA-35, DY01908LAJ, DY01200LABJQ, DY01983L, DY01869L (2)AJ, DY01869LAJ, DY01869L(3)AJ, DY01864LDJ, DY01864L, DY01864L(4) J-46, DY01872LAJ, DY01868LJ, DY01868L, DY01910LAJ, DY01863L(3)AJ, DY01906LDJ, DY01907LAJ, DY01984LJ, DY019003LABJ, DY01871LBJ, DY01805LABJ, DY01801LABJ, DY01863LABJ, DY019001LBJ-40, DY01905A(2)J, DY01904BD, DY01976A(2)BEJ, DY01976A(2)J, DY01809SW, DY01990, DY01903GC, DY01903BGC-35, DY01902GC, DY01951B-56, DY01951AC-56, DY01974-51, DY01909B, DY01908, DY01903, DY01902C, DY01901, DY01980AC-35, DY01972BDE, DY01972BDEC, DY01983, DY01802E-35, DY01874-46, DY01868, DY01809, DY01875D, DY01871, DY01873, DY01906DJ, DY02609GC, DY02608GC, DY02608L, DY02609, DY02608, DY02681, DY02683Q, DY02608LGC, DY02681C-51, DY01908LABJ, DY0215L-46, DY01216LA-46, DY01213LAJ-46, DY01408LAJ-46, DY01409LJ, DY01303LQ-36, DY01303LQ-41, DY01303LQ-44, DY01303LQ-46	41631 - Wheelchair, attendant/occupant-driven, bimanual-chain-operated, collapsible	-

Signature: 

Date: 2021.2.25

Position: GM

Place: Foshan / China

