



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 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-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.

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
SRN: CN-MF-000003324

Product Information

Name: Walker
Model: See Annex
GMDN: See Annex
Basic UDI-DI: 697000639DYWALKER01JX
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: 2023.09.04

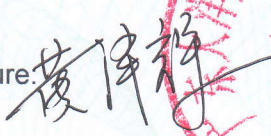
Name: Huang Zehui Place: Foshan / China
Position: GM



Annex

Product Name	Model	GMDN	Basic UDI-DI
Walker	DY04912L-5, DY04912L-2.5, DY04919L, DY04913L, DY04915L, DY04962L, DY04916L, DY04917L, DY04918L, DY04963L, DY04914L, DY04961L, DY04964L, DY04965L-5, DY04965L, DY04912L(S)-5, DY04913L(S), DY04966L(S)-2.5, DY04966L(S)	37951 - Disability assistive walker, non powered, foldable	697000639DYWALKER01JX

Signature:



Date:

2023.09.04

Position: GM

Place: Foshan / China

