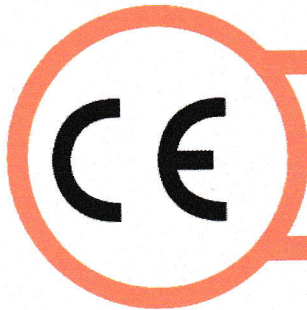




DECLARATION OF CONFORMITY

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, ISO 10993-1:2018, EN ISO
10993-5:2009, EN ISO 10993-10:2013,
EN ISO11199-1:1999

Remark

The declaration of conformity is valid in connection
with the release technical document
[CE-MDR-TCF006](#).

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 SHUNKANGDA MEDICAL TECH
CO.,LTD
Address: Pingnan Industrial Area , Guicheng Nanhai
District , 528251 Foshan City,Guangdong P.R. China

Product Information

Name: Walker
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:  *Yu Jinwei*

Date: *APR 7th 2021*

Name: Yu Jinwei

Place: Foshan / China

Position: GM

Annex

Product Name	Model	GMDN	Basic UDI-DI
Walker	CA811L, CA811LG, CA811L-Y, CA8115L, CA812L, CA812L-C, CA812LW, CA812LG, CA812LMG, CA812LSG, CA8124LG, CA8125L, CA8126LG, CA8127LG, CA8128L, CA8128LS, CA814LG, CA815LG, CA816L, CA816LG, CA8163L, CA817LG, CA819LL, CA819LM, CA819LS, CA821L, CA821L(variant), CA821LS, CA821LW, CA8211L, CA8212L, CA8213L, CA823L, CA824L, CA8241L, CA8242L, CA8246L, CA826L, CA828L, CA829L, CA818L, CA827CX, CA8272TX, CA8273, CA8273W, CA8274CX, CA8275, CA8276, CA8773, CA8773F, CA8776, CA810L, CA810L-4, CA810LD-5, CA8112L, CA8114LG-44, CA811L-5, CA811LG-5, CA8122LG-3, CA8122LG-4, CA8122LG-5, CA8123LG-3, CA812LXS, CA816LG-5, CA8211LW-55, CA821L-5, CA8243LL, CA8243LM, CA8243LS, CA8244L-3, CA824L-4, CA825, CA875, CA8117LG-44, CA8118, CA8116LG	37961	-

Signature: *Yu Rui Zhao* Date: *Apr 7th 2021*

Position: GM Place: *Foshan / China*

