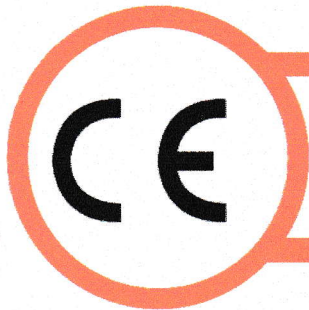




DECLARATION OF CONFORMITY

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,
ISO11199-2:2005

Remark

*The declaration of conformity is valid in connection
with the release technical document
[CE-MDR-TCF002](#).*

*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: Rollator

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: 

Name: Yu Jinwei Place: Foshan / China
Position: GM



Annex

Product Name	Model	GMDN	Basic UDI-DI
Rollator	C8860L, CA8611L, CA861L, CA862L, CA871L, CA873L, CA874, CA8741L, CA8761L, CA880, CA8801, CA8821W, CA882L, CA882LW, CA882W, CA8851L, CA8861L, CA8862L, CA8863L, CA8865L, CA8882L, CA888L, CA891L, CA892, CA894, CA8761L, CA881L, CA883L, CA884L, CA885L, CA8871L, CA887L, CA889L, CA891, CA893, CA8616L-KD, CA8617-KD, CA8870L, CA8864L, CA8880L, CA8854L	37951	-

Signature: Xu Rui Zhuo

Date: Apr 7th 2021

Position: GM

Place: Tashan / china

