



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: *Foshan / china*

