



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

Add: 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 ISO 20417: 2021,
EN ISO 15223-1: 2021,
EN ISO 10993-1:2020,
EN ISO 10993-5:2009,
EN ISO 10993-10:2013,
ISO 11199-1:1999,
ISO 11199-2:2005,
ISO 11199-3:2005

Remark

*The declaration of conformity is valid in connection
with the release technical document
MDR-Y1206-06.*

*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 KAIYANG MEDICAL EQUIPMENT
CO., LTD.

Address: 3 of No. 21. The 3rd Hongling Road,
Shishan Town, Nanhai District, Foshan City,
Guangdong Province, China

SRN: CN-MF-000008258

Product Information

Name: ROLLATOR/WALKER

Model: See Annex

EMDN: Y1206

Basic UDI-DI: 69404248006SH

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: NOV 15TH, 2022

Position: GENERAL MANAGER

Place: Foshan / China

佛山凯洋医疗器械有限公司
FOSHAN KAIYANG MEDICAL
EQUIPMENT CO., LTD.

Liao Youfeng

Annex

Product Name	Model	Basic UDI-DI
ROLLATOR/ WALKER	KY9141L,KY9142,KY9143,KY9144L,KY9144L-A,KY9144L-B, KY9144L(S),KY9145L,KY9146L,KY9148L,KY9148L-A,KY9149L, KY9160L,KY9158L,KY9159L KY912L-2",KY912L-2.5",KY912L-3",KY912L-5", KY912L-5(S),KY913L,KY913L(S),KY914L-5", KY915L,KY915L(S),KY916L,KY917L,KY918L,KY919L,KY961L, KY962L,KY963L, KY964L,KY964LR,KY965L,KY965L-2.5",KY965L-5",KY965L-5"(N), KY966L(S),KY966L(S)-2.5", KY966L(S)-3",KY967L, KY968, KY970,KY971,KY972R, KY9701,KY9702,KY9703	69404248 006SH

Signature:

Date: NOV 15TH, 2022

Position: GENERAL MANAGER

Place: Foshan / China

Liao Youfeng
佛山凯洋医疗器械有限公司
FOSHAN KAIYANG MEDICAL
EQUIPMENT CO., LTD.