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 ISO 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN ISO 11199-2: 2021

Remark
The declaration of conformity is valid in connection with the release technical document CE/MDR-Y120612-01.
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 HCT Medical Equipment Co.,ltd
Address: No.501 of 19 Building,Daxing Liandong U Valley, No. 4, Xiangshun Road, Danzao Town, Nanhai District, Foshan, Guangdong, China
SRN: CN-MF-000022837

Product Information

Name: Rollator
Model: See Annex
EMDN: Y120612
Basic UDI-DI: 697353654rollator001XL
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:2024.8.8

Position: GM Place: Foshan/China

Annex

Name	Model
Rollator	HCT-9166A, HCT-9166B, HCT-9266A, HCT-9102B, HCT-9102D, HCT-9102E, HCT-9102H, HCT-9102HW, HCT-9102J, HCT-9102S, HCT-9226, HCT-9226S, HCT-9137, HCT-9137A, HCT-9137B, HCT-9137C, HCT-9137D, HCT-9137DW, HCT-9137E, HCT-9137F, HCT-9137G, HCT-9124, HCT-9124A, HCT-9188, HCT-9188B, HCT-9103, HCT-9123, HCT-9123B, HCT-9210A, HCT-9210C, HCT-9104, HCT-9201A,HCт-9201B, HCT-9201C, HCT-9201E, HCT-9291, HCT-9291B, HCT-9291C, HCT-9291D, HCT-9291E, HCT-9292, HCT-9292B, HCT-9292C, HCT-9292D, HCT-9130 HCT-9298, HCT-9298-12, HCT-9189, HCT-9123C, HCT-9123D, HCT-9124C, HCT-9124D, HCT-9102D-12, HCT-9201EKD, HCT-9291F, HCT-9124E, HCT-9291-12, HCT-9123B-N, HCT-9293, HCT-9201KD, HCT-9102N, HCT-9137G-KD, HCT-9137DW-KD, HCT-9137H, HCT-9291N, HCT-9270, HCT-9290, HCT-9189L, HCT-9105, HCT-9271, HCT-9290A, HCT-9290D, HCT-9210AH, HCT-9124B, HCT-9123A-12, HCT-9123N, HCT-9210F, HCT-9210F-8, HCT-9210D-8, HCT-9298-12A, HCT-9102F, HCT-9189S, HCT-9189H, HCT-9273, HCT-9274, HCT-8010, HCT8020, HCT-8030, HCT-9105KD, HCT-9188D , HCT-9275, HCT-9276, HCT-9277, HCT-9278, HCT-9279, HCT-9280, HCT-8040, HCT-8050,HCT-8060, HCT-8070, HCT-8080

EU DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer

Name	:	Foshan HCT Medical Equipment Co.,ltd
Address	:	No.11,Dongyang 4th Road, Southern China Hardware Industry Base,
Country	:	Danzao Town, Nanhai District, Foshan City, Guangdong Province, China

European Representative

Name	:	**SUNGO Europe B.V**
Address	:	Olympisch Stadion 24,1076DE Amsterdam,
Country	:	Netherlands
Product group	:	Rollator
Model code	:	HCT-9123, HCT-9123A, HCT-9291, HCT-9210F, HCT-9210F-8 Refer to DMA product code 101 (S/V), 101 OFFROAD (S/V), 104 (S,V), 203 D, 203 DB
Classification	:	Class I, According to Rule 1， Annex VIII, Regulation (EU)2017/745

Conformity Assessment Procedure : Annex II+III of Regulation(EU)2017/745

Basic UDI-DI : 697353654rollator001XL

We, the manufacturer, herewith declare that the above mentioned products meet the requirements of the Medical Device Regulation (EU) 2017/745 and the following harmonized standards:

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, ISO 17966:2016

Signed for and on behalf of: Foshan HCT Medical Equipment Co., Ltd

Place: Foshan,Guandong,China

Date of issue: 16th Sep, 2024

Signature & Stamp:

Name: Lu YongHua

Position: General Manager