



# 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 ISO 15223-1: 2021  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013

## Remark

The declaration of conformity is valid in connection  
with the release technical document  
CE/MDR-Y120606-01.

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.11,Dongyang 4th Road, Southern  
China Hardware Industry Base, Danzao Town,  
Nanhai District, Foshan City, Guangdong Province,  
China.

SRN:CN-MF-000022837

## Product Information

Name: Rollator

Model: See Annex

EMDN: Y120606

GMDN: 38702

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:

2022.9.16

Position: GM

Place: Guangdong/China





## Annex

Product Name	Model
Rollator	9166A, 9166B, 9266A, 9102B, 9102D, 9102E, 9102H, 9102HW, 9102J, 9102S, 9226, 9226S, 9137, 9137A, 9137B, 9137C, 9137D, 9137DW, 9137E, 9137F, 9137G, 9124, 9124A, 9188, 9188B, 9103, 9123, 9123B, 9210A, 9210C, 9104, 9201A, 9201B, 9201C, 9201E, 9291, 9291B, 9291C, 9291D, 9291E, 9292, 9292B, 9292C, 9292D, 9130



## 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-9291, HCT-9210C, HCT-9210A, HCT-9201E  
Refer to DMA product code 101 (S/V), 104 S, 203 A, 203B, 103 A

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: 16<sup>th</sup> Sep,2022

Signature & Stamp:

Name: Lu YongHua

Position: General Manager

