

# **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 HardwareIndustry Base, Danzao Town, Nanhai District, FoshanCity, Guangdong Province, China.

SRN:CN-MF-000022837

Product Information

Name: Rollator

Model: See Annex

EMDN: Y120606 GMDN: 38702

Basic UDI-DI: 697353654rollator001XL

Classification: Classl, 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

Signature

standards above.

Date:

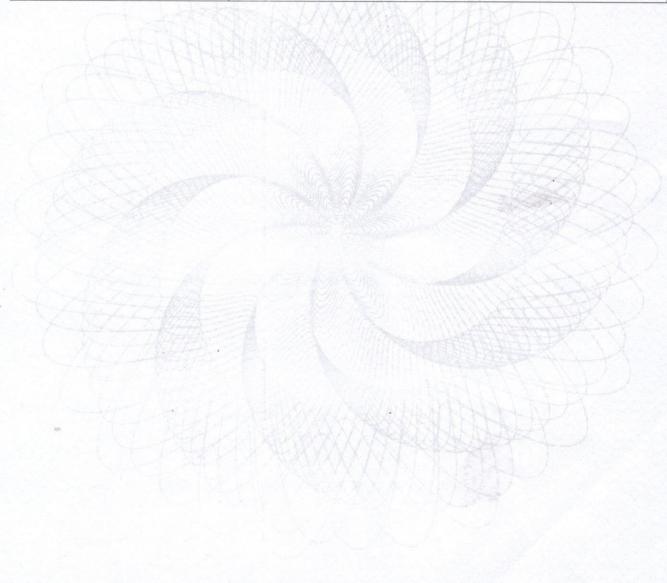
,22.9.16

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

