



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 M Ü C K Y

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



DMA

K O M P E N Z A Č N Í P O M Ů C K Y



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
Refer to DMA product code 101 (S/V), 104 S, 203 A, 203B
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,2022

Signature & Stamp:

Name: Lu YongHua
Position: General Manager

