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

