DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:	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
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam,Netherlands

Product Name: Rollator

Model: 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

SRN: _____-_____ **Basic UDI-DI:** _____-_____

Classification:	Class I
Rule:	Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure:	Annex II+III of Regulation (EU) 2017/745

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

EN ISO 14971: 2012

EN ISO 15223-1: 2016

EN 1041:2008+A1:2013

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

ISO 11199-2:2005

Signature: Lu Yong Hua

Name / Position: Lu Yonghua / GM

Date: 2020.5.13

Place: Guangdong / China