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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, 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-HCT-001.

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

Product Information

Name: Rollator
Model: HCT-9188, HCT-9102B, HCT-9226, HCT-9166B, HCT-9291D
GMDN: 37951
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: Lu Yonghua Date: 2022.4.12

Name: Lu Yonghua Place: Foshan / China

Position: GM