



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: HANGZHOU FUYANG HONGWEI METAL PRODUCT LIMITED
COMPANY

Address: Liaoan village, Wanshi town, Fuyang district, Hangzhou, Zhejiang
province, China.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Rollator

Model: 723600000 721100100, SA1311005, WA006SIL-1, ABS10257-
29, FSR8BLK, TA3903, 2470 2410, 4004, 4005, 243851,
V0504029, 346-NPU, 347-NPU, V0504026, TW001R, SA1312005,
TA3908.

Classification: Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Annex II+III of Regulation (EU) 2017/745

Assessment

Procedure:

SRN: /

Basic UDI-DI: /

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 1041: 2008+AI 2003

EN ISO 15223-1: 2016 EN ISO 11199-2:2006 *SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

Signature: 
Name / Position: HU AIFEN / GM

Date: 2020.7.28
Place: Zhejiang China



Authorized Signature (S)



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: HANGZHOU FUYANG HONGWEI METAL PRODUCT
LIMITED COMPANY

Address: Liaoan village, Wanshi town, Fuyang district, Hangzhou,
Zhejiang province, China.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Commode chair

Model: 530100000, 11239, 11240, S70004000-BL18, 5019w2p,
401001, 14200, 14002, 14000, 512DBAPH, 512PSB, 521AD.

Classification: Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Annex II+III of Regulation (EU) 2017/745

Procedure:

SRN: /

Basic UDI-DI: /

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 1041: 2008/ EN ISO 15223-1: 2016

Signature: 
Name / Position: HU AIFEN / GM
Date: 2020.7.18
Place: Zhejiang China

*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*



Authorized Signature (S)