



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Lotus NL B.V
Koningin Julianaplein 10,le
Verd,2595AA, The
Hague,NetherlandsAmsterdam,
Netherlands
SRN: NL-AR-000000121

Manufacturer

Name:
Zhenjiang U-Nurse Medical Equipment Co., Ltd.

Operation Address: Building 16,Central R&D
Zone,Science and Technology Industrial
Park,Development Zone,No99, Jing15th Road,New
District,Zhenjiang City,Jiangsu Province,China

Registered Address:Building 2,Central R&D
Zone,Science and Technology Industrial
Park,Development Zone,No99, Jing15th Road,New
District,Zhenjiang City,Jiangsu Province,China

Conformity Assessment

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

Applicable Standards

EN ISO 14971: 2019,
EN 20417:2021,
EN ISO 15223-1: 2021,
ISO 10993-1:2018,
EN ISO 10993-5:2009,
EN ISO 10993-10:2013

Product Information

Name: COMMODE CHAIR
Model:UN4001,UN4002,UN4003,UN4004,UN4005,UN4006U
N4007,UN4008,UN4009,UN4010,UN4011,UN4012,UN4013,U
N4014,UN4015,UN4016,UN4017,UN4018,UN4019,UN4020

SRN: CN-MF-000013494

Basic UDI-DI: 697479546 commodechair96

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF01.

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.

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

Signature:

Miya zhan

Position:GM

Date:

2022.11.8

镇江优能医疗器械有限公司
ZHENJIANG YU-NORSE MEDICAL EQUIPMENT CO., LTD.

Place: Jiangsu/China

