



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Lotus NL B.V
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Netherlands
SRN: NL-AR-000000121

Conformity Assessment

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

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2021
EN 1041:2008+A1:2013
ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 11199-2:2021

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

Product Information

Name: SHOWER CHAIR

Model:UN7008,UN7009

SRN: CN-MF-000013494

Basic UDI-DI: 697479546showerchairSU

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:  Date: 2023.8.8
镇江优能医疗器械有限公司
ZHENJIANG YU-NUO MEDICAL EQUIPMENT CO., LTD.

Position: GM

Place: Jiangsu/China

