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 ISO 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 13485

Intended use

The Commode Chair is used for excreting of people who are experiencing illness, injury or disability, it can be used at home or hospital.

Manufacturer

Name: Zhongshan Kangdebao(KDB) Rehabilitation Equipment Co., Ltd.
Address: Card 1, No.5, 24#, Longcheng Road, Dongsheng Town, Zhongshan City, Guangdong Province, China
SRN: CN-MF-000020594

Product Information

Name: COMMODE CHAIR
Model: KDB-607, KDB-608, KDB-609, KDB-610, KDB-697, KDB-698, KDB-699, KDB-890, KDB-898, KDB-892, KDB-893, KDB-894, KDB-895, KDB-601, KDB-602, KDB-603, KDB-613, KDB-615, KDB-631, KDB-632, KDB-633, KDB-635, KDB-681, KDB-682, KDB-683, KDB-691A (5060), KDB-691B, KDB-692, KDB-693, KDB-695, KDB-696, KDB-881, KDB-882, KDB-883, KDB-885, KDB-891, KDB-896, KDB-897, KDB-899, KDB-901, KDB-902, KDB-697B, KDB-698A, KDB-699A, KDB-699C, KDB-890B
EMDN: Y091212
GMDN: 40539
Basic UDI-DI: 697353766ZBY600UQ
Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y091212-01.
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.

Declaration

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

NAME AND LAST NAME: WEI JIAN LIN
Signature: WEI JIAN LIN Date: 2022-11-18

Position: GENERAL MANAGER

Place: Zhongshan/China