DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aanden IJssel, The 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
ISO 10993-1:2018
ISO 10993-5:2009
ISO 10993-10:2021
ISO 10993-23:2021
ISO 13485:2016

Intended use

The lift and transfer device is for transferring the lower body paralysis, leg and foot inconvenience patients or the elderly from bed, wheelchair, seat, or toilet seat. This device greatly relieved caregivers' work. It improves the efficiency of nursing work, and reduces the nursing risk.

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: lift and transfer device
Model: KDB-506
EMDN: V080502
Basic UDI-DI: 697353766YWJ500Y4
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-V080502-01.

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.

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: 2023.03.17

Position: General Manager Place: Zhongshan/China