DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert GmbH,

Harffstr. 47,40591 Düsseldorf, Germany

SRN:DE-AR-000010869

Manufacturer

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971: 2019

EN ISO 20417:2021

EN ISO 15223-1: 2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN ISO 13485:2016

EN 60601-2-52:2010+ AC:2011+A1:2015

EN 60601-1-2:2015+ A1:2020

EN 60601-1:2006+ A1:2013+AC:2014+ A12:2014 +A2:2020

Product Information

Name: Medical Bed

Model: S2, S2L, S2W, S3, S4UP, S5, S5UP, S301, S502, S502UP, S503, S503UP, S703, S703.TL, S704UP,SWOP HYDRO2, SWOP HYDRO3F, SWOP HYDRO2L, M1, BLIGHT502, BLIGHT503 or customized size.

GMDN: 34870

Basic UDI-DI : 697459027SWOPS502HA, 697459027SWOPS503HC , 697459027SWOPS2LRW, 697459027SWOPS24E , 697459027SWOPS34G, 697459027SWOPS54L , 697459027SWOPS5UPNG, 697459027SWOPS301GW

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

BASIC UDI-DI:

8436601770813, 8436601773470, 8436601770820, 8436601770790, 8436601770806, 8436601773500, 8436601773517, 8436601773524, 8436601773531

Declaration

2022.9.1

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-BEHB-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: 2022.9.1

Position: GM Place: Foshan/China