



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V. ,
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2909VA Capelle aan den 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 15223-1:2016

EN 1041:2008+A1: 2013

ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-FC-05.

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.

Manufacturer

Name: Sunshine Healthcare Co., Ltd

Address: No. 31 Jihua Eastern road, Nanhai, Foshan, China

Product Information

Name: Commode chair / toilet seat raisers

Model: BA387A (500 Deluxe) , BA312A (510 E)

GMDN: 40539

Basic UDI-DI:

BA387A (500 Deluxe) 697493158BA387ADP

BA312A (510 E) 697493158BA312AC5

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

Declaration

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: 2024/8/30

Position: GM 旭日器材有限公司 Place: Guangdong/China