



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 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-23:2021

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-Y091203-07.*

*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: Zhongshan A&J Medical Equipment Co., Ltd.
Address: L3 Shenghui South Road, Nantou Town,
Zhongshan City, Guangdong, 528427 China.
SRN: CN-MF-000038649

Product Information

Name: Toilet seat raiser
Model: 580;508 Super
EMDN: Y091203
Basic UDI: 697786346seatraiserS5
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: 杰医疗器材工

Date: 2023.8.30

Position: GM

Place: Guangdong/China

