



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 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/A11:2021
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5:2009/A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-001

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.

File No.: MDR-TCF-001-08

Manufacturer

Name: ZHONGSHAN A&J MEDICAL
EQUIPMENT CO., LTD.

Address: 3 Shenghui South Road, Nantou Town,
Zhongshan City, Guangdong, 528427 China
SRN: CN-MF-000038649

Product Information

Name: Shower/Commode Chair, Mobile

Model: 512 (Commode chair, mobile), 512 NWHD,
808, 808 C, 808 W

EMDN: Y091203

Basic UDI-DI: 697786346COMMODECHAIR25

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:

Li chun Sen

Position: GM

Date: 2025/9/3



Place: Guangdong/China