



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

**Name:** SUNGO Europe B.V.

**Address:** Fascinatio Boulevard 522, Unit 1.7,  
2909VA Capelle aan den IJssel, The Netherlands

**SRN:** NL-AR-000000247

## Manufacturer

**Name:** Zhongshan A&E Machinery Industry  
Co., Ltd.

**Address:** NO.9 shenghui South Road Nantou  
Town Zhongshan city Guangdong province  
China.

**SRN:** CN-MF-000038650

## 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

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021

## Product Information

**Name:** Commode Chair

**Model:** 3514, 512E, 513, 513S, 521W

**EMDN:** Y091203

**Basic UDI-DI:** 697789798CommodeChairLC

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

## 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

## 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:2025.7.23

Position: GM

Place: zhongshan/China

