



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

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: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V08050101-03.

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: Zhangjiagang Medi Medical Equipment Co., Ltd

Address: Room 614 of Guotai New World Square, No.19 of Renmin East Road, Yangshe Town, Zhangjiagang City, Jiangsu Province, China

SRN:

Product Information

Name: Patient Transfer Stretcher

Model : YA-PS02E, YA-PS03, YA-PS15, YA-PS05, YA-PS06, YA-PS07, YA-PS07B, YA-PS08, YA-PS09, YA-PS10, MK-AT01, YA-CS01

EMDN: V08050101

Basic UDI-DI: /

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: 2023/4/24

Position: GM Place: Zhangjiagang/China