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

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: Delivery Table
Model : MC-D01,MC-D07,MC-D02,MC-D03,YA-EC-U06,MC-D19,MC-D05,MC-D04,MC-D09
EMDN: V080699
Basic UDI-DI: /
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

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
EN 60601-1:2006/ A2:2020
EN 60601-1-2:2015/A1:2020

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080699-04.

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.

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

Digitally signed by Botnaru Andrei
Date: 2023.06.08 14:25:26 EEST
Reason: MoldSign Signature
Location: Moldova