



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,, 2909
VA Capelle aan den IJssel
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: 2013
BS EN 60601-2-52:2010+A1:2015
IEC 60601-1:2012
IEC60601-1-2:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080601-01.

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: JIANGSU YONGXIN MEDICAL
EQUIPMENT CO., LTD
Address: LEYU TOWN, ZHANGJIAGANG CITY,
JIANGSU PROVINCE, CHINA
SRN:CN-MF-000019424

Product Information

Name : ELECTRIC HOSPITAL BED
Model : YXZ-C2,YXZ-C3, YXZ-C5
EMDN : V080601
Basic UDI-DI : 697557517ebed69
Classification: Class I, According to Rule 13, 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: 2021.12.9



Position: GM

Place: Jiangsu/China



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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-V080602-02.

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: JIANGSU YONGXIN MEDICAL EQUIPMENT CO., LTD
Address: LEYU TOWN, ZHANGJIAGANG CITY, JIANGSU PROVINCE, CHINA
SRN:CN-MF-000019424

Product Information

Name : MANUAL HOSPITAL BED
Model : YX-D-1, YX-D-2, YX-D-3, YX-D-4, YX-D-5, YX-D-6, YXZ-001, YXZ-002, YXZ-003, YXZ-004, YXZ-005, YX-B-1, YX-B-2, YX-B-3, YX-B-4, YX-C-1, YX-C-2, YX-C-3, YX-C-4
EMDN : V080602
Basic UDI-DI : 697557517mbed7Z
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

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Signature: _____ Date: 2021.12.9



Position: GM

Place: Jiangsu/China



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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: JIANGSU YONGXIN MEDICAL
EQUIPMENT CO., LTD
Address: LEYU TOWN, ZHANGJIAGANG CITY,
JIANGSU PROVINCE, CHINA
SRN:CN-MF-000019424

Product Information

Name : STRETCHER
Model:
YXZ-D-A,YXZ-D-B,YXZ-D-C,YXZ-D-D,YXZ-D-E
YXZ-D-F,YXZ-D-G,YXZ-D-H,YXZ-D-I,YXZ-D-J
YXZ-D-K,YXZ-D-L,YXZ-D-M,YXZ-D-N,YXZ-D-P
EMDN : V08050101
Basic UDI-DI : 697557517stretcherDD
Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

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Position: GM

Place: Jiangsu/China



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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-V9098-04.

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.

Manufacturer

Name: JIANGSU YONGXIN MEDICAL
EQUIPMENT CO., LTD

Address: LEYU TOWN, ZHANGJIAGANG CITY,
JIANGSU PROVINCE, CHINA

SRN: CN-MF-000019424

Product Information

Name : MEDICAL TROLLEY

Model : SM-001, SM-002, SM-003, SM-004, SM-005,
SM-006, SM-007, SM-008, SM-009, SM-010, SM-011
SM-012, SM-013, SM-014, YXZ-E-1, YXZ-E-2,
YXZ-E-3, YXZ-E-4, YXZ-F, YX-1, YX-2, YX-3, YX-4,
YX-5, YX-6, YXZ-ET600, YXZ-ET750, YXZ-ET850,
YX-MT750, YX-MT850C, YX-MT8502, YX-MT850,
YX-AT750

EMDN : V9098

Basic UDI-DI : 697557517TrolleyMZ

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

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Signature:

Date: 2021.12.9



Position: GM

Place: Jiangsu/China