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
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 IEC 60601-2-46:2019
IEC 60601-1:2012
IEC60601-1-2:2014

Remark
The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12011202-02.
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 Rooe Medical Technology Co.,Ltd
Address: NO.19,Renmin East Road,YangShe Town,Zhangjiagang City(Cathay Pacific Plaza)Z1310
SRN:

Product Information

Name: Electric Operation Table
Model: AOT302A, AOT8801A, AOT700, AOT8801A Pro, AOT303B, AOT500
EMDN: Z12011202
Basic UDI-DI: /
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: 2023.1.9

Position: GM Place: Jiangsu/China

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Fascinatio Boulevard 522, Unit 1.7,
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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
IEC 60601-1:2012
IEC60601-1-2:2014
IEC60601-2-41:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z120107-03.

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 Rooe Medical Technology Co.,Ltd
Address: NO.19,Renmin East Road,YangShe Town,Zhangjiagang City(Cathay Pacific Plaza)Z1310
SRN:

Product Information

Name: Operation Light
Model : AKL-K700/500 , AKL-G700/500 , AKL-LED·D78/D78 , AKL700/500-III, AKL-LED·MSZ4
EMDN: Z120107
Basic UDI-DI: /
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: 2023.1.19

Position: GM Place: Jiangsu/China

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
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-V08050101-01.

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 Rooe Medical Technology Co.,Ltd
Address: NO.19,Renmin East Road,YangShe Town,Zhangjiagang City(Cathay Pacific Plaza)Z1310
SRN:

Product Information

Name: Stretcher

Model: EA-3A, EA-3B, EA-3C, EA-3G, EA-7A, EA-11A02

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: 2023.1.9

Position: GM Place: Jiangsu/China

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
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 60601-2-52:2010+A1:2015
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015+A1:2021
EN 62366-1:2015

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 Rooe Medical Technology Co.,Ltd
Address: NO.19,Renmin East Road,YangShe Town,Zhangjiagang City(Cathay Pacific Plaza)Z1310
SRN: CN-MF-000033285

Product Information

Name: ELECTRIC HOSPITAL BED
Model:BAE508, BAE503, BAE502, BIC800, BIC601, BAE5091, BAE509, BAE509 Pro, BAE505, BIC801, BAE504, BAE303, BAE304, BAE308, BAE312, ALDR100B, ALDR100D
EMDN: V080601
Basic UDI-DI: 697606231002J2
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:2023.11.17

Position: GM

Place: Jiangsu/China