DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-28.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Spine Board
Model: CR-J01, CR-J03, CR-J07
GMDN: 13673
Basic UDI-DI: 697456774CR-J01MW
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-29.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Aluminum Moldable Splint
Model: CR-06
GMDN: /
Basic UDI-DI: 697456774CR-J01MW
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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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
ISO 10993-1: 2018
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-EMSRUN-24.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Chest Seal
Model: CR-CS01
GMDN:
Basic UDI-DI: 697456774CR-CS01TR
Classification: Class I
SRN: CN-MF-000008968
Intended use: Chest Seal is suitable for First-Aid hemostasis and trauma nursing.Composed of Outer package bag, chest seal.

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:2021.09.30

Position: GM Place: WUXI CHINA

DECLARATION OF CONFORMITY

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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
ISO 10993-1: 2018
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-EMSRUN-24.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: COMPRESSED GAUZE
Model: 4.5”X4.1y
GMDN:
Basic UDI-DI: 6974567744.5"X4.1yEA
Classification: Class I
SRN: CN-MF-000008968
Intended use: The compressed gauze is intended to be used to stop bleeding from wounds caused by injuries in pre-hospital emergency situations.

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:2021.09.30

Position: GM Place: WUXI, CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 62366-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Mouth-to-mouth face mask
GMDN: 13818
Model: CR-CPR K
Basic UDI-DI: 697456774CR-PP01W5
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI,CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Silicone Tube
Model: 15566，15567，15568
GMDN: /
Basic UDI-DI: 697456774155669Q
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI,CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Manual Suction Unit
Model: CR-MSU1
GMDN: /
Basic UDI-DI: 697456774CR-MSU1ZB
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-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

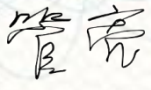
Name: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Oxygen regulator
Model: O2REGBM
GMDN: 31760
Basic UDI-DI: 697456774O2REGBM3U
Classification: Class I

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:202.09.30

Position: GM

Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-07.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Firsr Aid Kit
Model: CR-Q7
GMDN: 44047
Basic UDI-DI: 697456774CR-QB001AFS
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

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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: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 62366-1: 2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-08.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Tape
Model: CR-AT01、CR-AT02
GMDN: 16866
Basic UDI-DI: /
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 62366-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-09.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Emergency blanket
Model: 130*210cm, 140*210cm, 150*210cm, 160*210cm
GMDN: 10416
Basic UDI-DI: 697456774130*210cm5F
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 62366-1：2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-10.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Scissors
Model: 5cm,10cm,12cm,14cm,15cm,16cm,19cm
GMDN: 13481
Basic UDI-DI: 6974567745cmXX
Classification: Class I
SRN: CN-MF-000008968
Intended use: Scissors is a type of scissors used by paramedics and other emergency medical personnel to quickly and safely cut out tape or bandage.

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:2021.09.30

Position: GM Place:WUXI, CHINA

DECLARATION OF CONFORMITY

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SRN: NL-AR-000000247

Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-11.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Manual resuscitator
Model: CR-RM01、CR-RM02
GMDN: 36086
Basic UDI-DI: 697456774CR-RM01W4
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-12.

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

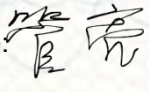
Name: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Oropharyngeal Airway
Model: CR-OA01
GMDN: 42424
Basic UDI-DI: 697456774CR-OA01TK
Classification: Class I
SRN: CN-MF-000008968
Intend use: Oropharyngeal Airway is intended used for maintenance of upper airway patency.

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:2021.09.30

Position: GM

Place: WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN ISO 5364：2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-13.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Nasopharyngeal airway
Model: CR-B1
GMDN: 42422
Basic UDI-DI: 697456774CR-B1M6
Classification: Class I

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:202.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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SRN: NL-AR-000000247

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-14.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Ambulance stretcher
Model:CR-10, CR-11, CR-12, CR-13, CR-14, CR-15, CR-16, CR-17, CR-18, CR-21
GMDN: 35843
Basic UDI-DI: 697456774CR-11KN
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

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Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-15.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Scoop stretcher
Model:CR-S10, CR-S11, CR-S12, CR-S13
GMDN: 38052
Basic UDI-DI: 697456774CR-S10PC
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-16.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Stair stretcher
Model:CR-001, CR-H1, CR-H2, CR-H3, CR-H4, CR-H5, CR-H6
GMDN: 13818
Basic UDI-DI: 697456774CR-001HZ
Classification: Class I

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:202.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-17.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Folding stretcher
Model:CR-F10, CR-F11, CR-F12, CR-F13, CR-F14, CR-F15, CR-F16, CR-F17, CR-F18, CR-F19, CR-F20, CR-F21, CR-F22, CR-F23, CR-F24, CR-F25, CR-F26, CR-F27
GMDN: 13818
Basic UDI-DI: 697456774CR-F10MB
Classification: Class I

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:202.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-19.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Gauze dressing
Model: FA-1060, SWAB100T, SWAB100X
GMDN: 48130
Basic UDI-DI: 697456774FA-1060DW
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-20.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Adhesive bandage
Model:CR-AB01, CR-AB02
GMDN: 34864
Basic UDI-DI: 697456774CR-AB01QN
Classification: Class I
Intend use: Adhesive bandage is used for Rapid hemostasis and trauma nursing.

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:

Position: GM Place: WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-21.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: *Gloves*
Model:CR-GV01, CR-GV02
GMDN: 56286
Basic UDI-DI: 697456774CR-GV01V4
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-22.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Isolation stretcher
Model: CR-IS01
GMDN: /
Basic UDI-DI: 697456774CR-IS01V3
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-23.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Tourniquet
Model: CR-ED01
GMDN: 58128
Basic UDI-DI: 697456774CR-ED01RU
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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
ISO 10993-1: 2018
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-EMSRUN-24.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Bandage
Model: CR-BD01
GMDN: 47011
Basic UDI-DI: 697456774CR-BD01R7
Classification: Class I
SRN: CN-MF-000008968
Intended use: The Bandage is intended to be used to stop bleeding from wounds caused by injuries in pre-hospital emergency situations.

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:2021.09.30

Position: GM Place: WUXI, CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-25.

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

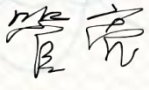
Name: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Head Immobilizer
Model: CR-02, CR-03
GMDN: 45258
Basic UDI-DI: 697456774CR-02KM
Classification: Class I

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:2021.09.30

Position: GM

Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-26.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Cervical Collar
Model: CR-05
GMDN: 41039
Basic UDI-DI: 697456774CR-05KT
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-EMSRUN-27.

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: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Traction Splint
Model: CR-Y1
GMDN: 62041
Basic UDI-DI: 697456774CR-Y1PB
Classification: Class I

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:2021.09.30

Position: GM Place:WUXI CHINA