



Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: ZHANGJIAGANG XIEHE MEDICAL APPARATUS&INSTRUMENTS CO.,LTD.
Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town,
Zhangjiagang City, Jiangsu 215600, China

European Authorised Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Emergency Stretcher & Stretcher Accessories
Model: - see annex

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870001DN

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Medical Device Regulation (EU) 2017/745) and the following harmonized standards.

EN ISO 14971: 2012

EN ISO 15223-1: 2016

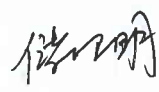
ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN 1041: 2008

EN 62366-1:2015

Signature: 

Position:  G.M.

Date: 2021.6.28

Annex

Emergency Stretcher

YXH-1A1	YXH-1L	YXH-2T2	YXH-4D	YXH-6D
YXH-1A2	YXH-1M	YXH-3A	YXH-5A	YXH-C1
YXH-1A3	YXH-1K	YXH-3A2	YXH-5B	YXH-C2
YXH-1A5	YXH-1N(A)	YXH-3A3	YXH-5C	YXH-2R2
YXH-1A6	YXH-1N(B)	YXH-3A5	YXH-5D	XH-4C
YXH-1B1	YXH-1N(C)	YXH-3B	YXH-5E	XH-5C
YXH-1B2	YXH-A2	YXH-3B2	YXH-5F	ATHENA I
YXH-1B3	YXH-1A6L	YXH-3B3	YXH-5K	ATHENA II
YXH-1C	YXH-1A6A	YXH-3C	YXH-5N	ATHENA III
YXH-1D	YXH-1A6B	YXH-3D	YXH-5G	VENUS I
YXH-1DL	YXH-1A6C	YXH-3D2	YXH-5H	VENUS II
YXH-1E	YXH-1A6D	YXH-3E	YXH-5L	VENUS III
YXH-1EF	YXH-1A6E	YXH-3E2	YXH-5M	VENUS IV
YXH-1EL	YXH-1A6G	YXH-3E3	YXH-5O	NEPTUNE
YXH-1F1	YXH-1A6H	YXH-3F	YXH-5P	HESTIA
YXH-1F1B	YXH-1A6K	YXH-3G	YXH-C3	HESTIA I
YXH-1F2	YXH-1A6M	YXH-2L2	YXH-C4	HERMES I
YXH-1F3	YXH-1A6N	YXH-3K	YXH-6A	HEPHAESTUS II
YXH-1F4	YXH-4E	YXH-3H	YXH-6B	HESTIA III-B
YXH-1F4A	YXH-1A6A-2	YXH-7N	YXH-6C	HERMES II
YXH-1G	YXH-2A	YXH-4A	One-piece Basket Stretcher YXH-4G	
YXH-1GL	YXH-2B	YXH-4B	Two-piece Basket Stretcher	
YXH-1H	YXH-2C	YXH-4C	HEPHAESTUS III	
EC1	EC2	YXH-7A	YXH-7B	YXH-7C

Emergency Accessories

Safety Belts	Spider Straps	S01	S02	XH-509
XH-510	XH-511	XH-512	2 HOOKS IV POLE	
4 HOOKS IV POLE				





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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Vacuum Stretcher

Model: - YXH-7D

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870010DP

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

Conformity assessment procedure: Annex II+III

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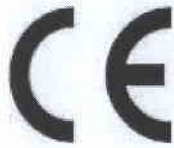
Position:



总经理 G.M.

Date:

2021. 6. 28



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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Extrication Device

Model: - YXH-7H

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870002DQ

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

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Signature: 储明

Position: 总经理



Date: 2021. 6. 28



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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Cervical Collar

Model: - XH-17 XH-19 Philadelphia Collar

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870006DY

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

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EN ISO 10993-10: 2013

EN 1041: 2008

EN 62366-1:2015

Signature: 张明

Position: 总经理



G.M.

Date: 2021.6.28



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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Emergency Blanket

Model: - XH-18

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870005DW

Classification: I

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Date: 201. 6. 28





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European Authorised Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Manual Suction
Model: - YXH-MSR

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870007E2

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Resuscitator

Model: - XH-KB04 XH-KB05 XH-KB06 XH-KB07 XH-KB09 XH-KB10 YXH-M01

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870008E4

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

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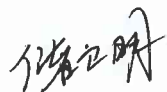
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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Emergency Scissor

Model: - XH-21 XH-22

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870004DU

Classification: I

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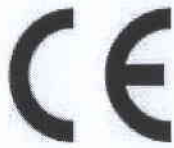
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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Splint

Model: - YXH-9A YXH-9B XH-15A XH-15B YXH-9 YXH-10 YXH-8B

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870003DS

Classification: I

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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Emergency Trolley

Model: - XH-ET-62526S XH-85037B XH-85011A2 XH-75071A-LS XH-62512B3
XH-80056J XH-T18C21-DT XH-LS50YC XH-Y01 XH-Y02 XH-002T XH-005

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870009E6

Classification: I

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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Head Immobilizer

Model: - XH-16A XH-16B XH-16C

SRN: - CN-MF-000008449

Basic UDI-DI: - 6974580870011DR

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

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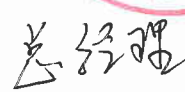
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