



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: Cervical Collar
Model: - XH-17 XH-19 Philadelphia Collar

SRN: -

UDI-DI: -

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

On behalf of SUNGO Europe office, I confirmed we are the EOR of the company who issue this document



[Handwritten Signature]

Signature: *[Handwritten Signature]*

Authorized Signature (S)
Position: *[Handwritten Signature]* General manager

Date: 2020.6.29



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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: -

UDI-DI: -

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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EN 1041: 2008

EN 62366-1:2015

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Authorized Signature (S)



Signature: *[Handwritten Signature]*

Position: *总经理 General manager*

Date: *2020.6.29*



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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: -

UDI-DI: -

Classification: I

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

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Date: *2020.6.29*



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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: -

UDI-DI: -

Classification: I

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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: -

UDI-DI: -

Classification: I

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

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EN ISO 14971: 2012

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ISO 10993-1: 2018

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EN ISO 10993-10: 2018

EN 1041: 2008

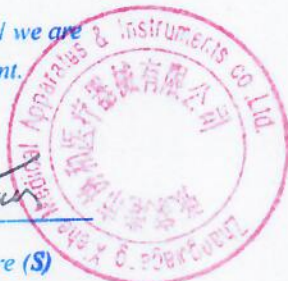
EN 62366-1:2015

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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: -

UDI-DI: -

Classification: I

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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: -

UDI-DI: -

Classification: I

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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: -

UDI-DI: -

Classification: I

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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: -

UDI-DI: -

Classification: I

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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: -

UDI-DI: -

Classification: I

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

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ISO 10993-1: 2018 *EU REP of the company who issue this document.*

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EN ISO 10993-10: 2013

EN 1041: 2008

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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: -

UDI-DI: -

*On behalf of SUNGO Europe office, I confirm
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Authorized Signatory

Classification: I

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- EN ISO 10993-10: 2013
- EN 1041: 2008
- EN 62366-1:2015



Signature: *[Handwritten Signature]*

Position: *[Handwritten Signature]* General manager

Date: *2020.6.29*

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-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				

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



[Handwritten Signature]

Authorized Signature (S)



*Confirmed we are
document.*

[Handwritten Signature]
Signature (S)