

# 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 ISO 20417:2021  
EN ISO 10993-1: 2020  
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-XH03-01.*

*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:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Vacuum Stretcher  
**Model:** YXH-7D  
**GMDN:** 13818  
**Basic UDI-DI:** 6974580870010DP  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

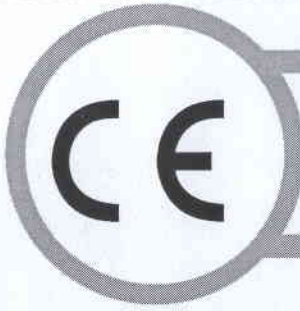
## Declaration

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: 2021

Position: G.M. Place: Zhangjiagang





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

**Applicable Standards**  
EN ISO 14971: 2019  
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EN ISO 20417:2021  
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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-XH07-01.*

*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:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Emergency Blanket  
**Model:** XH-18  
**GMDN:** 10416  
**Basic UDI-DI:** 6974580870005DW  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

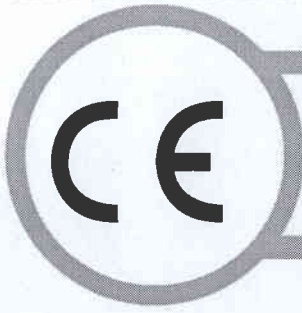
## Declaration

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: 2021



Position: G. M. Place: Zhangjiagang



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EN ISO 20417:2021  
EN ISO 10993-1: 2020  
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-XH06-01.

All the supporting documentation is retained at the premises of the manufacturer.

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## Manufacturer

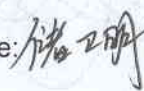
**Name:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Splint  
**Model:** YXH-9A YXH-9B XH-15A XH-15B YXH-9 YXH-10 YXH-8B  
**GMDN:** 43565&43588  
**Basic UDI-DI:** 6974580870003DS  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

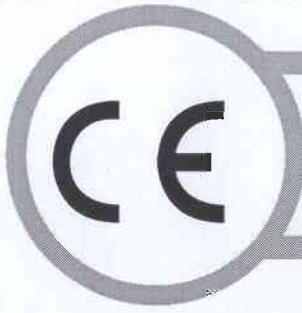
We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: 

Date: 2021.09.17



Position: G. M. Place: Zhangjiagang



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

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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-XH01-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

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## Manufacturer

**Name:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Emergency Stretcher & Stretcher Accessories  
**Model:** see Annex  
**GMDN:** 35892  
**Basic UDI-DI:** 6974580870001DN  
**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: 2021.9.17



Position: G.M. Place: Zhangjiagang

# Annex

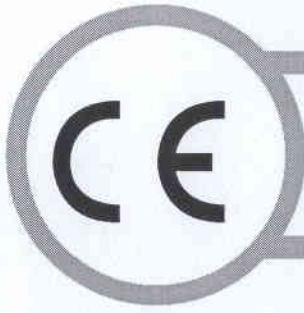
## Emergency Stretcher

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	YXH-5L-1
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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Annex II+III of Regulation (EU) 2017/745

Applicable Standards  
EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
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-XH11-01.

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: ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
SRN: CN-MF-000008449

## Product Information

Name: Manual Suction  
Model: YXH-MSR  
GMDN: 63644  
Basic UDI-DI: 6974580870007E2  
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: 2021.09.17

Position: G. M . Place: Zhangjiagang





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## Conformity Assessment

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

**Applicable Standards**  
EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
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-XH10-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

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## Manufacturer

**Name:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Resuscitator  
**Model:** XH-KB04 XH-KB05 XH-KB06 XH-KB07 XH-KB09 XH-KB10 YXH-M01  
**GMDN:** 41882  
**Basic UDI-DI:** 6974580870008E4  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

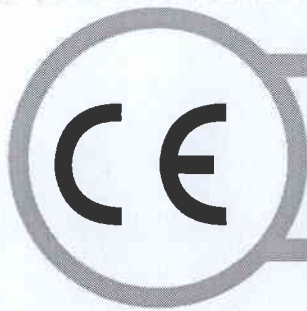
## Declaration

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: 2021.9.17

Position: G. M. Place: Zhangjiagang





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EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
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-XH04-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

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## Manufacturer

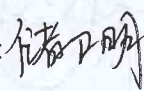
**Name:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Extrication Device  
**Model:** YXH-7H  
**GMDN:** 13673  
**Basic UDI-DI:** 6974580870002DQ  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

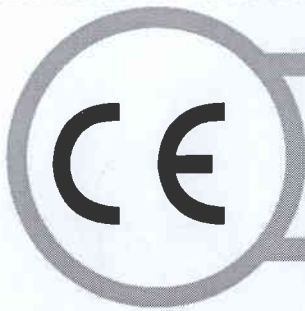
We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2021.9.17

Position: G.M. Place: Zhangjiagang







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**Conformity Assessment Procedure**  
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EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN 14683:2019

## Remark

*The declaration of conformity is valid in connection with the release technical document CEMDR-XH-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

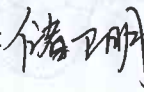
**Name:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Face Mask  
**Model:** 17.5\*9.5cm  
**GMDN:** 35177  
**Basic UDI-DI:** 697458087mask001A4  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

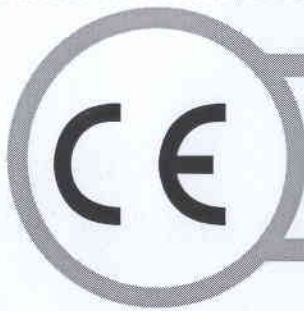
## Declaration

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: 2024.9.17

Position: G.M. Place: Zhangjiagang





# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

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

## Manufacturer

Name: ZHANGJIAGANG XIEHE MEDICAL  
APPARATUS AND INSTRUMENTS CO.,LTD  
Address: No.7th, Middle Xinzha Road, Zhashang  
Industrial Zone, Yangshe Town, Zhangjiagang City,  
Jiangsu 215600, China  
SRN: CN-MF-000008449

## Product Information

Name: Head Immobilizer  
Model: XH-16A XH-16B XH-16C  
GMDN: 45258  
Basic UDI-DI: 6974580870011DR  
Classification: Class I, According to Rule 1, Annex  
VIII, Regulation (EU) 2017/745

## 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 ISO 20417:2021  
EN ISO 10993-1: 2020  
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-XH02-01.

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.

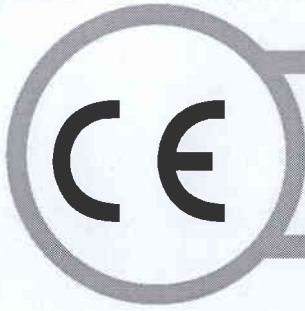
## Declaration

We herewith declare that the above-mentioned  
products meet the requirements of Medical Device  
Regulation (EU) 2017/745 and the applicable  
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Signature:  Date: 2021.9.17



Position: G. M. Place: Zhangjiagang



# DECLARATION OF CONFORMITY

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### Conformity Assessment Procedure

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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-XH05-01.*

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## Manufacturer

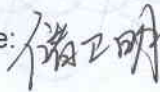
**Name:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD.  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
**SRN:** CN-MF-000008449

## Product Information

**Name:** Cervical Collar  
**Model:** XH-17 XH-19 Philadelphia Collar  
**GMDN:** 41039  
**Basic UDI-DI:** 6974580870006DY  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

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EN ISO 20417:2021  
EN ISO 10993-1: 2020  
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-XH08-01.

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## Manufacturer

Name: ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD  
Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
SRN: CN-MF-000008449

## Product Information

Name: Emergency Trolley  
Model: XH-ET-62526S XH-85037B XH-85011A2  
XH-75051A-LS XH-62512B3 XH-80056J  
XH-T18C21-DT XH-LS50YC XH-Y01 XH-Y02  
XH-002T XH005  
GMDN: 40542  
Basic UDI-DI: 6974580870009E6  
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: 

Position: G. M. Place: Zhangjiagang

