



# 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 62366-1:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y060306-07.*

*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: Xiamen Huakang Orthopedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue, Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Abdominal Binder  
EMDN: Y060306  
Model: BS013 BS014  
Basic UDI-DI: 697581676AB001G6  
Classification: Class I, According to Rule1, Annex VIII of EU Medical Device 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:

Position: GM

Date:

2024.11.25

Place:





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### Applicable Standards

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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 62366-1:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090618-06.*

*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: Xiamen HuakangOrthpedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City,361027 China  
SRN:CN-MF-000002290

## Product Information

Name : Ankle External Brace  
EMDN:Y090618  
Model: AS001 AS002 AS003 AS004 AS005 AS006  
AS007 AS008 AS009 AS010 AS011 AS012 AS013  
AS015 AS016 AS017 AS018 AS019 AS020  
Basic UDI-DI : 697581676AEB001GY  
Classification:Class I,According to Rule1,Annex  
VIII of EU Medical Device 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: 2025.03.13

Position: GM Place: Xiamen/China





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### 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 62366-1:2015

### Remark

The declaration of conformity is valid in connection  
with the release technical document  
CE/MDR-Y090612-02.

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: Xiamen Huakang Orthpedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Shoulder Arm Sling

EMDN: Y090612

Model: SL001 SL002 SL003 SL004 SL005 SL006  
SL007 SL008 SL009 SL010 SL011 SL012 SL013  
SL014 KB005

Basic UDI-DI: 697581676SAS001SM

Classification: Class I, According to Rule1, Annex  
VIII of EU Medical Device 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: 

Position: GM

Date: 2024.11.25

Place: 



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## Conformity Assessment

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### 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 62366-1:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090699-04.*

*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: Xiamen Huakang Orthopedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Cervical Collar  
EMDN: Y090699  
Model: CS001 CS002 CS003 CS004 CS005 CS006  
KB006  
Basic UDI-DI: 697581676CC001H3  
Classification: Class I, According to Rule1, Annex  
VIII of EU Medical Device 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:

Position: GM

Date:

2024.11.25

Place:





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### 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 62366-1:2015

### Remark

*The declaration of conformity is valid in connection  
with the release technical document  
CE/MDR-Y090612-05.*

*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: Xiamen HuakangOrthpedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Hand Splint  
EMDN:Y090612  
Model: FS001 FS002 FS003 FS004 FS005 FS006  
FS007 FS008 FS009 FS010  
WS001WS002WS003WS004WS00  
5WS006WS007WS008 WS009KB006  
Basic UDI-DI : 697581676HS001NA  
Classification:Class I,According to Rule1,Annex  
VIIIof EU Medical Device 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: 2025.03.13

Position: GM Place: Xiamen/China



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### 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 62366-1:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090699-01.*

*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: Xiamen Huakang Orthopedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Clavicle splint  
EMDN: Y090699  
Model: CB001 CB002 CB003  
Basic UDI-DI: 697581676CS001LK  
Classification: Class I, According to Rule1, Annex VIII of EU Medical Device 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:

Position: GM

Date: 2024.11.25

Place:





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### 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 62366-1:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090612-08.*  
*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: Xiamen HuakangOrthpedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Limb Brace  
EMDN:Y090612,Y090618  
Model: See Annex  
Basic UDI-DI : 697581676LB001KX  
Classification:Class I,According to Rule1,Annex VIII of EU Medical Device 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: 2025.03.13



Position: GM

Place: Xiamen/China

ANNEX

ES001 ES002 ES003 ES004 ES005 ES006 ES007 ES008 ES009 ES010 ES011 ES012 HA001 HA002 HA003  
HA004

KN001 KN002 KN003 KN004 KN005 KN006 KN007 KN008 KN009 KN010 KN011 KN012 KN013 KN014 KN015  
KN016 KN017 KN018 KN019 KN020 KN021

KN022 KN023 KN024 KN025 KN026 KN027 KN028 KN029 KN030 KN031 KN032 KN033 KB007 NS001 NS002  
NS003 NS004

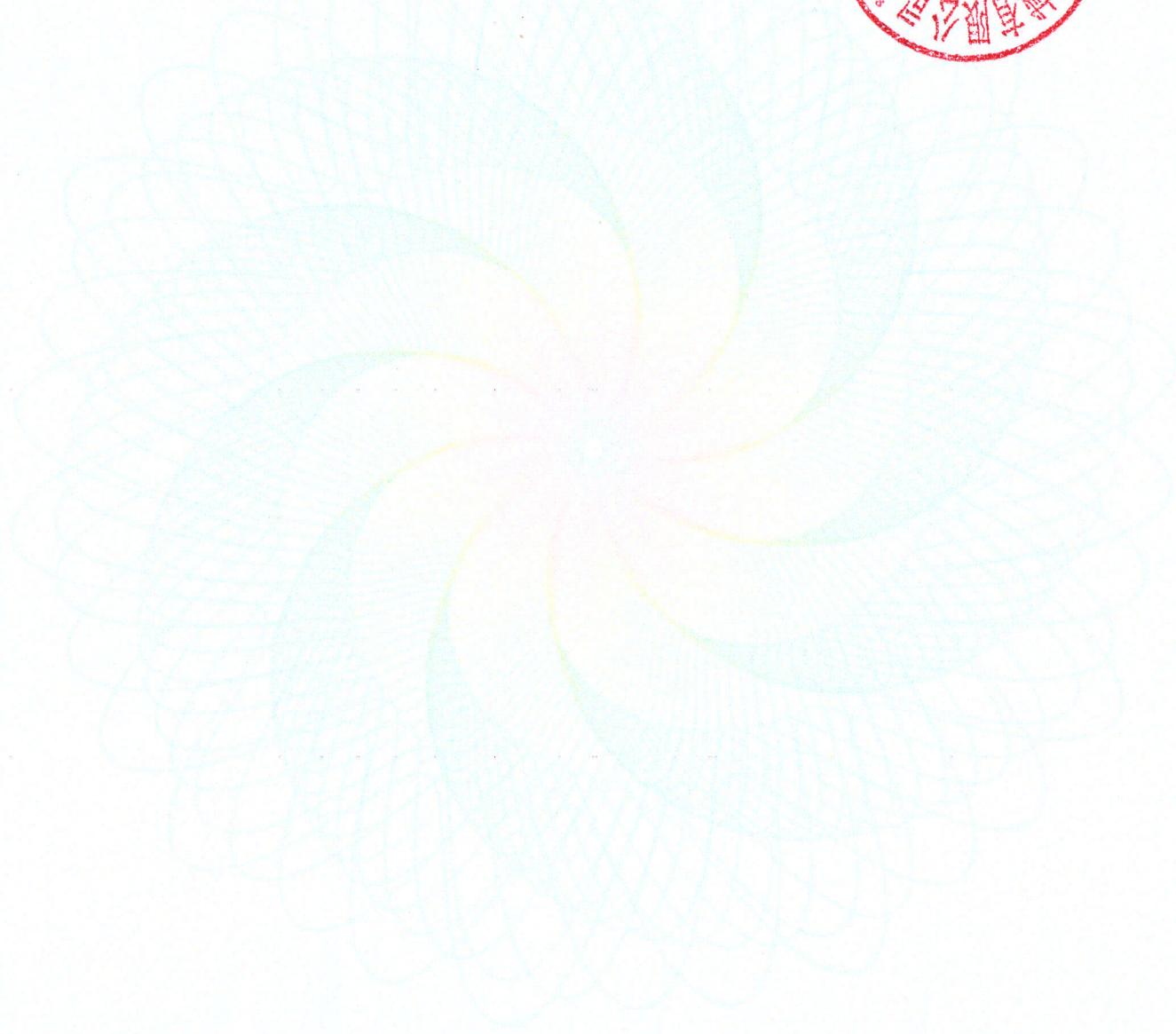
NS005 NS006 NS007 NS008 NS009 NS010 NS011 NS012 NS013 NS014

NS015 NS016 NS017 SH001 SH002 SH003 SH004 SH005 TS001 WK001 WK002

WK003 WK004 WK005 WK006 WK007 WK008 WK009 WK010 WK011 WK012

WK013 WK014 WK015 WK016 WK017 WK018 WK019 WK020 WK021 WK022

WK023 WK024 WK025 WK026 WK027 WK028 KB001 KB002 KB003





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### Applicable Standards

EN ISO 14971: 2019  
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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 62366-1:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090699-03.*

*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: Xiamen HuakangOrthpedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Lumbo-Sacral Back Brace  
EMDN:Y090699  
Model: BS001 BS002 BS003 BS004 BS005 BS006  
BS007 BS008 BS009 BS010 BS011 BS012 BS015  
BS016 BS017 BS018 BS019 BS020 BS021 BS022  
BS023 BS024 BS025 BS026 BS027 BS028 BS029  
BS030  
Basic UDI-DI : 697581676LSBB0012K  
Classification:Class I,According to Rule1,Annex  
VIIIof EU Medical Device 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: 2025.03.13

Position: GM  Place: Xiamen/China



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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

## Remark

The declaration of conformity is valid in connection  
with the release technical document  
CE/MDR-Y090618-09.

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: Xiamen HuakangOrthpedic Co., Ltd.  
Address: 2F, Building #13, No. 2881 Dongfu Avenue,  
Haicang District, Xiamen City, 361027 China  
SRN:CN-MF-000002290

## Product Information

Name: Fixed Walker  
EMDN: Y090618  
Model: See Annex

Basic UDI-DI: 697581676FixedWalker5J

Classification: Class I, According to Rule1, Annex  
VIII of EU Medical Device 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: 2025.04.02

Position: GM

Place: Xiamen / China

## ANNEX

WK001 17" Tall Pneumatic Walker  
WK001-B 17" Tall Pneumatic Walker  
WK001-C 17" Tall Pneumatic Walker  
WK002 11" Short Pneumatic Walker  
WK002-B 11" Short Pneumatic Walker  
WK002-C 11" Short Pneumatic Walker  
WK003 Tall Gel Walker  
WK004 Short Gel Walker  
WK005 17" Tall Summer ROM Walker  
WK006 17" Mesh Foam Walker  
WK007 11" Breathable Foam Walker  
WK008 17" ROM Walker  
WK008-B 17" ROM Walker  
WK009 17" ROM Pneumatic Walker  
WK009-B 17" ROM Pneumatic Walker  
WK009-C 17" ROM Pneumatic Walker  
WK010 11" ROM Pneumatic Walker  
WK010-B 11" ROM Pneumatic Walker  
WK010-C 11" ROM Pneumatic Walker  
WK011 17" Pneumatic Walker  
WK012 11" Pneumatic Walker  
WK013 17" Fixed Walker  
WK014 11" Fixed Walker  
WK015 17" Poly Fixed Walker  
WK016 11" Poly Fixed Walker  
WK017 17" Poly Pneumatic Walker  
WK018 11" Poly Pneumatic Walker  
WK019 17" Poly Pneumatic Walker  
WK020 11" Poly Pneumatic Walker  
WK021 17" Poly Pneumatic Walker  
WK022 11" Poly Pneumatic Walker  
WK023 17" Poly Fixed Walker  
WK024 11" Poly Fixed Walker  
WK025 17" Pneumatic Walker  
WK026 11" Pneumatic Walker  
KB001 12" Teenagers Poly Fixed Walker  
KB008 Paediatric Walker Boot Bracing  
KB009 Pneumatic Paediatric Walker Boot Bracing

