CE CE

Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: Xiamen Huakang Orthopedic Co., Ltd

Address: Floor 3, no. 555, shanbian road, dongfu town, haicang district, xiamen city, PR China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Ankle External Brace

Model: - AS001 AS002 AS003 AS004 AS005 AS006 AS007 AS008 AS009 AS010 AS011 AS012 AS013 AS014 AS015 AS016 AS017 AS018 AS019

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.

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

Sungo global service

Authorized Signature (S)

EN ISO 14971: 2019
EN ISO 15223-1: 2016
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 1041: 2008+A1:2013
EN 62366-1:2015

Signature:

Position: General Manager

Date: MAY 22.,2020

CE CE

Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: Xiamen Huakang Orthopedic Co., Ltd

Address: Floor 3, no. 555, shanbian road, dongfu town, haicang district, xiamen city, PR China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Lumbo-Sacral Back Brace

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

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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Sungo global service

Authorized Signature (S)

Signature:

Position: General Manager

Date: MAY 22.,2020

CE CE

Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: Xiamen Huakang Orthopedic Co., Ltd

Address: Floor 3, no. 555, shanbian road, dongfu town, haicang district, xiamen city, PR China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Abdominal Binder

Model: - BS013 BS014

SRN: -

UDI-DI: -

Classification: I

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

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Sungo global service

Authorized Signature (S)

Signature:

Date: MAY 22.,2020

Position: General Manager

Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: Xiamen Huakang Orthopedic Co., Ltd

Address: Floor 3, no. 555, shanbian road, dongfu town, haicang district, xiamen city, PR China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Cervical Collar

Model: - CS001 CS002 CS003 CS004 CS005 KB004

SRN: -

UDI-DI: -

Classification: I

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

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EN 62366-1:2015

Sungo global service

Authorized Signature (S)

Signature:

Position: General Manager

Date: MAY 22, 2020

CE CE

Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: Xiamen Huakang Orthopedic Co., Ltd

Address: Floor 3, no. 555, shanbian road, dongfu town, haicang district, xiamen city, PR China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Clavicle splint

Model: - CB001 CB002 CB003

SRN: -

UDI-DI: -

Classification: I

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

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Sungo global service

Authorized Signature (S)

Signature:

Position: General Manager

Date: MAY 22.,2020

Declaration of Conformity

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Manufacturer

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European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Limb Brace

Model: - ES001 ES002 ES003 ES004 ES005 ES006 ES007 HA001 HA002 HA003 HA004 KN001 KN002 KN03 KN004 KN005 KN006 KN007 KN08 KN009 KN010 KN011 KN012 KN013 KN14 KN015 KN016 KN017 KN018 KN019 KN020 KN021 KN022 KN023 KN024 KN025 KN026 KB007 NS001 NS002 NS003 NS004 NS005 NS006 NS007 NS008 NS009 NS010 NS011 NS012 NS013 NS014 NS015 NS016 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

SRN: -

UDI-DI: -

Classification: I

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Sungo global service

Authorized Signature (S)

Signature:

Position: General Manager

Date: MAY 22.,2020

CE **Declaration of Conformity** CE

Regarding 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: Hand Splint

Model: - FS001 FS002 FS003 FS004 FS005 FS006 FS007 FS008
WS001 WS002 WS003 WS004 WS005 WS006 WS007 WS008
WS009 KB006

SRN: -

UDI-DI: -

Classification: I

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EN 62366-1:2015

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Sungo global service

Authorized Signature (S)

Signature:

Position:

Date: MAY 22,2020

Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: Xiamen Huakang Orthopedic Co., Ltd

Address: Floor 3, no. 555, shanbian road, dongfu town, haicang district, xiamen city, PR China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Shoulder Arm Sling

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

SRN: -

UDI-DI: -

Classification: I

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

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Sungo global service

Authorized Signature (S)

Signature:

Position: General Manager

Date: MAY 22.,2020