



e-life International Co., Ltd.
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EC Declaration of Conformity

in accordance to Medical Device Regulation (EU)2017/745 Article 19, Annex IV

Manufacturer:

Name: e-life International Co., Ltd.

Address: Address: 7F, No.1, Baosheng Rd., Yonghe Dist., New Taipei City 234, Taiwan (R.O.C.)

SRN: TW-MF-000009901

European Authorized Representative:

Name: MOSS GmbH SRN : DE-AR-000005430

Address: Schiffgraben 41. 30175 Hannover, Germany

Swiss Authorized Representative:

Name: MDSS CH GmbH CHRN : CHRN-AR-20001035

Address: Laurenzenvorstadt 61 5000 Aarau Switzerland

UK Responsible Person:

Name: MDSS-UK RP Ltd

Address: 6 Wilmslow Road, Rusholme, Manchester M14 5TP, UK

Product name: Splint Products

Product information: See Appendix A

Classification: Class I

Intended purpose: Immobilization and /or angle adjustment for control range of motion of body part that might suffer from surgery, injuries or degeneration.

Rule: According to Rule1, Annex VIII (Rule1: All non invasive devices are classified as class I, also not suitable for Rule 2 to 4 and Special Rules) of Regulation (EU) 2017/745, based on the intended use of Splint Products it shall be Class I.

Conformity assessment procedure: Annex 11+111

We, the manufacturer, declare our product comply the general safety and performance requirements to Annex I of the regulation (EU) 2017/745 and to the medical device class I according to the regulation (EU) 2017/745, Annex VIII, Chapter III, Rule 1.

Conformity compliance is confirmed by the conformity assessment in accordance with the regulation (EU) 2017/745 Annex I, Chapters 1 to 3.

The Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Signature: _____

Name/Position: Kenny Lee/ CEO & OWNER

Date: 2025/01/03

Place: New Taipei City/ Taiwan (R.O.C.)



Appendix					
Basic UDI-DI	GMDN No	GMDN ITEM	Old Catalogue No	New Catalogue No.	Product name
471230298CHPY	43445	Thoracolumbosacral spine orthosis, rigid	-	TH-MCH0004	JEWETT BRACE
471230298ELQE	42782	Elbow joint orthosis component	-	TH-MELPO03	POST-OP ELBOW BRACE WITH HANDGRIP

