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**EU DECLARATION OF CONFORMITY OF MEDICAL DEVICE
DRAWN UP BY THE MANUFACTURER**

Manufacturer: Pro Medicare S.r.l. with registered office and operational headquarters
in Mesagne (BR) Via Montagna

General Device Name: "ERMES modular postural system for children and TIPCO indoor base
with relative accessories "

UDI-DI BASIC: 805571347ERMESTIPCOKM

Manufacturers SRN: IT-MF-000022537

Devices Codes: As per Appendix "All.Dic.Con.Erm.Tip. EN Rev.3 06/12/2022"

Pursuant to Article 19 of the EU Regulation 2017/745 of the European Parliament and Council, the undersigned, Dr. Franco Cariolo, Sole Director and Legal Representative of Pro Medicare S.r.l., manufacturer of standard class I medical devices according to the rules provided, having performed the conformity assessment as prescribed by the above Regulation and having fully complied with the procedures established in Chapter V Section 2 and Annex II and III,

ensures and declares that

- the devices comply with the requirements set out in article 5 and in Annex I, therefore can be lawfully placed on the market and into service after affixing the CE Mark as required in Article 20 of the EU Regulation 2017/745.
- Pro Medicare S.r.l. is responsible for the design, manufacture, packaging, and labeling.

Mesagne (BR), 06/12/2022

Pro Medicare S.r.l.

Sole Director and Legal Representative

Pro Medicare s.r.l.

C.F. e P. Iva 01803920741 - Cap. Soc. € 10.000,00 (i.v.) - C.C.I.A.A. n° 102141 - Reg. Trib. N° 18256



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Annex to the Declaration of
Conformity

All.Dic.Con.Erm.Tip. EN
Rev.3 06/12/2022

Range	Code - Description of the Device
ERMES-TIPCO	TPC-(Mis.) - Tipco indoor frame TECHNICAL FEATURES: TPC: Tipco indoor frame Mis.: size Sizes: TPC: 1; 2; 3
	ERM (Mis.)-M/D-BL/FC/VN - Pediatric Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system Mis.: size M: cushion midi; D: cushion deep BL: blue; FC: fuchsia; VN: wine Sizes: ERM: 01; 02; 03; 04
ERMES-TIPCO	ERM 3/4D/S(Mis.)-BL/FC/VN - Thoracic Support for Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system 3: Flat Pad; 4: Contoured Pad D/S: Right/Left Mis.: size BL: blue; FC: fuchsia; VN: wine Sizes: 3: 1(7x7,5); 2(7x8,5); 3(8x10); 4(10x12) 4: 1(6x9,5); 2(7x11); 3(8x13); 4(10x16)
	ERM C01/C02/C03(Mis.)-E/F-BL/FC/VN - Headrest for Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system C01: Comfort Headrest; C02: Anatomic Headrest; C03: 3 Piece pads supportive Headrest Mis.: size E: detachable; F: fixed BL: blue; FC: fuchsia; VN: wine Sizes: C01: S; M; G C02: XS; S; M C03: 1;2
ERMES-TIPCO	ERM 16(Mis.)-BL/FC/VN - Harness Trunk for Ermes Postural System ERM 28-(Mis.) - Harness Trunk for Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system 16: Dynamic Butterfly Harness; 28: Ches pad Mis.: size BL: blue; FC: fuchsia; VN: wine Sizes: 16: XS; S; M 28: 1; 2; 3
	ERM 19/19A-(Mis.) - Harness pelvic for Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system 19: Pelvic belt; 19A: Countered pelvic belt Mis.: size Sizes: 19: 1; 2; 3 19A: 1; 2
ERMES-TIPCO	ERM 14G/T(Mis.) - Detachable tray for Ermes Postural System ERM 14G-A(Mis.) - Detachable tray for Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system 14G: Tray grey; 14T: Tray transparent; 14G-A: Tray grey larger version for daily activities Mis.: size Sizes: 14G/14T/14G-A: 2;3;4
	ERM 15S/U-(Mis.)BL/FC/VN - Calf Panel for Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system 15: Calf panel S/U: Separate/Unique Mis.: size BL: blue; FC: fuchsia; VN: wine Sizes: 15: 2; 3; 4
ERMES-TIPCO	ERM 15F-(Mis.)BL/FC/VN - Calf Strap anterior/posterior padded for Ermes Postural System TECHNICAL FEATURES: ERM: Pediatric ermes postural system 15F: Calf Strap anterior/posterior padded Mis.: size BL: blue; FC: fuchsia; VN: wine Sizes: 15F: 2; 3; 4
	D04-X01-Y Eolo TECHNICAL FEATURES: D04 High chair device Eolo X: color 0: blue/green pastel; 6: purple/dove grey 01: Eolo Y: size

	<p><u>Sizes:</u> Y: 1;2;3</p>
Eolo	<p>S04-X000Y-Z Thoracic Support for Eolo <u>TECHNICAL FEATURES:</u> S04 Accessories High chair Eolo X: color 0: blue/green pastel; 6: purple/dove grey Y: type of thoracic support -> Y=1 fixed type A flat thoracic support, Y=2 fixed type B flat thoracic support, Y=3 type A right wrap-around thoracic support, Y=4 type A left wrap-around thoracic support, Y=5 type B right wrap-around thoracic support, Y=6 type B left wrap-around thoracic support Z: size <u>Sizes:</u> Z: 1;2;3,4</p>
Eolo	<p>S04-X0007-Z Dynamic butterfly harness for Eolo <u>TECHNICAL FEATURES:</u> S04 Accessories High chair Eolo X: color 0: blue/green pastel; 6: purple/dove grey Z: size <u>Sizes:</u> Z: 1;2;3</p>
Eolo	<p>S04-X0008-Y Pelvic belt for Eolo <u>TECHNICAL FEATURES:</u> S04 Accessories High chair Eolo X: color 0: blue/green pastel; 6: purple/dove grey Y: size <u>Sizes:</u> Y: 1;2;3</p>
Eolo	<p>S04-X0009-Y Contoured Pelvic Belt for Eolo <u>TECHNICAL FEATURES:</u> S04 Accessories High chair Eolo X: color 0: blue/green pastel; 6: purple/dove grey Y: size <u>Sizes:</u> Y: 1;2</p>
Eolo	<p>S04-X0010-Y Dynamic abduction harness for Eolo <u>TECHNICAL FEATURES:</u> S04 Accessories High chair Eolo X: color 0: blue/green pastel; 6: purple/dove grey Y: size <u>Sizes:</u> Y: 1 (XS);2 (S);3 (M)</p>
Eolo	<p>S04-X0011-Y Headrest for Eolo <u>TECHNICAL FEATURES:</u> S04 Accessories High chair Eolo X: color 0: blue/green pastel; 6: purple/dove grey Y: size <u>Sizes:</u> Y: 1 (M);2 (G)</p>
Eolo	<p>S04-X0012-Y Padded abductor wedge for Eolo <u>TECHNICAL FEATURES:</u> S04 Accessories High chair Eolo X: color 0: blue/green pastel; 6: purple/dove grey Y: size <u>Sizes:</u> Y: 1;2;3</p>

NOTE: All sizes are expressed in centimeters (cm)