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

Manufacturer: Pro Medicare Srl with registered office and operational headquarters
in Mesagne (BR) Via Montagna

General Device Name: "Base posturale manuale serie Adacta"

UDI-DI BASIC: 805660010ADACTAWW

Manufacturers SRN: IT-MF-000022537

Devices Codes: As per Appendix "All.Dic.Con.Ada. EN Rev.2 31/10/2023"

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), 31/10/2023

Pro Medicare S.r.l.

Sole Director and Legal Representative


SRL
L'Amministratore Unico

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.Ada. EN
Rev.2 31/10/2023

Range	Code - Description of the Device
ADACTA	<p>A-LC/LR/-(Mis.)-BL/MG/RS/TI - Modular Frame for Positioning system - Adacta</p> <p><u>TECHNICAL FEATURES:</u> A: Adacta frame LC: Liga Foldable Frame; LR: Liga rigid frame Mis.: size BL: blue; MG: magenta; RS: red; TI: titanium <u>SIZES:</u> LC/LR: US(30x38); XXS(35x38); XS(35x42); XS1(38x45); S(41x46); M(41x50); M1(44x50); L(47x46); XL(47x50)</p>
ADACTA	<p>A-LEO-(Mis.)-BL/RS/RO/TR/TI - Modular Frame for Positioning system - Adacta Leo</p> <p><u>TECHNICAL FEATURES:</u> A: Adacta Frame LEO: Leo rigid frame Mis.: size BL: blue; RO: pink; RS: red; TR: turquoise; TI: titanium <u>SIZES:</u> LEO: US(30x38); XXS(35x38); XS(35x42); XS1(38x45); S(41x46); M(41x50); M1(44x50)</p>
ADACTA	<p>A-LEO-V-(Mis.)-TI/NE - Modular Frame for Positioning system - Adacta Leo Vip</p> <p><u>TECHNICAL FEATURES:</u> A: Adacta Frame LEO: Leo rigid frame V: Vip Mis.: size TI: titanium; NE: black <u>LEGENDA MISURE:</u> LEO: XS1(38x45); S(41x46); M(41x50); M1(44x50)</p>
ADACTA	<p>A-LLC/LLR/-(Mis.)-BL/RO/RS/TR/TI - Modular Frame for Positioning system - Adacta Liga Light</p> <p><u>TECHNICAL FEATURES:</u> A: Adacta Frame LLC: Liga Light foldable frame; LLR: Liga Light rigid frame Mis.: size BL: blue; RO: pink; RS: red; TR: turquoise; TI: titanium <u>SIZES:</u> LLC/LLR: US(30x38); XXS(35x38); XS(35x42); XS0(38x42); XS1(38x45); S(41x46); M(41x50); M1(44x50); L(47x46); XL(47x50)</p>
ADACTA	<p>A-ERG-(Mis.)-BL/FC/VN - Giò Ermes</p> <p><u>TECHNICAL FEATURES:</u> A: Adacta Frame ERG: Rigid frame Mis.: size BL: blue; FC: fuchsia; VN: wine <u>SIZES:</u> ERG: 2 (25x38,5), 3 (30x34,5), 6 (35x42,5)</p>
ADACTA	<p>A-ERR-(Mis.)-BL/RO/VN - Adacta Giò</p> <p><u>TECHNICAL FEATURES:</u> A: Adacta Frame ERR: Rigid frame Mis.: size BL: blue; RO: pink; VN: bordeaux <u>SIZES:</u> ERR: 1 (25x34,5), 2 (25x38,5), 3 (30x34,5), 4 (30x38,5), 5 (35x38,5), 6 (35x42,5), 7 (38x42,5)</p>
ADACTA	<p>A-KLIM-(Mis.)-GR - Adacta Klim</p> <p><u>TECHNICAL FEATURES:</u> A: Adacta Frame Mis.: size GR: grey <u>SIZES:</u> KLIM: XXS(35x38); XS(35x42); XS1(38x46); S(41x46); M(41x50); M1(44x50)</p>
ADACTA	<p>KIT-BR-(Mis.) - Kit tubular-armrests</p> <p>Mis.: size <u>SIZES:</u> 1:25mm; 2:30mm</p>

ADACTA	KIT-ME-P(mis) DX/SX - Kit of hardware multi-adjustable detachable pediatric dx/sx <u>Mis.:</u> size <u>SIZES:</u> 1: arm support pad (8x22)/hip guide pad (25x10) ; 2: arm support pad (10x30)/hip guide pad (30x12) <u>DX:</u> right; <u>SX:</u> left
ADACTA- VERSA	KIT-SP(mis)(dx/sx)Z - Removable upper limb postural unit adjustable in width/height/depth for ABS lateral kit <u>Mis.:</u> size <u>Z:</u> L: Long; empty field: short <u>DX:</u> right; <u>SX:</u> left <u>SIZES:</u> 1: small; 2: big
ADACTA-VERSA	A-VTC/VTR-(Mis.)-RO/TR-B/M/D-E/S - Integrating positioning system Adacta-Versa "TITTI" <u>TECHNICAL FEATURES:</u> <u>A:</u> Adacta Frame <u>VTC:</u> Integrating positioning system for children Adacta-Versa TITTI foldable; <u>VTR:</u> Integrating positioning system for children Adacta-Versa TITTI rigid; <u>Mis.:</u> size <u>RO:</u> pink; <u>TR:</u> turquoise <u>B:</u> Inserto Seat Basico; <u>M:</u> Inserto Seat Mediano; <u>D:</u> Inserto Seat Domino <u>E:</u> Inserto Back Effecto; <u>S:</u> Inserto Back Supporto <u>SIZES:</u> <u>VTC/VTR:</u> US(30x38); XXS(35x38); XS(35x42); XS0(38x42)
ADACTA-VERSA	A-ZC/ZR-(Mis.)-B/M/D-E/S - Integrating positioning system Adacta-Versa "ZEUS" <u>TECHNICAL FEATURES:</u> <u>A:</u> Adacta Frame <u>ZC:</u> Integrating positioning system Adacta-Versa ZEUS for adult titanium foldable; <u>ZR:</u> Integrating positioning system Adacta-Versa ZEUS for adult titanium rigid <u>Mis.:</u> size <u>B:</u> Inserto Seat Basico; <u>M:</u> Inserto Seat Mediano; <u>D:</u> Inserto Seat Domino <u>E:</u> Inserto Back Effecto; <u>S:</u> Inserto Back Supporto <u>SIZES:</u> <u>ZC/ZR:</u> XS1(38x45); S(41x46); M(41x50); M1(44x50); L(47x46); XL(47x50)
ADACTA	PMD X-Y - Lower limb postural unit Adacta Frame <u>TECHNICAL FEATURES:</u> <u>X:</u> knee angle type -> G-90P; OPT G-75P; OPT G-01P; G-75A; OPT G-90A; OPT G-01A; OPT G-03A; G-02S; OPT G-90S; OPT G-75S; OPT G-00-75; OPT G-00-90; OPT G-02S; G-03A; OPT G-75A <u>Y:</u> colour BL, RO, RS, TI, TR

NOTE: All sizes are expressed in centimeters (cm)