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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: "Postura Versa"

UDI-DI BASIC: 805660010POSTURAVERSAS3

Manufacturers SRN: IT-MF-000022537

Devices Codes: As per Appendix "All.Dic.Con.Pos.Ver. EN Rev.5 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.Pos.Ver. EN
Rev.5 31/10/2023

Range	Code - Description of the Device
VERSA	PMD 1 (Mis.) 11/12A/12P/13D/13S/14/15/16/17 - Pelvis Positioning Systems - Versa TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 1: Versa Positioning system Mis.: size 11: rectangular shape flat padding; 12A/P: rectangular shape anterior/posterior wedge padding; 13D/S: rectangular shape lateral RH/LH wedge padding; 14: rectangular shape anti-thrust with abductor padding; 15: rectangular shape contoured padding; 16: rectangular shape anti-thrust padding; 17: rectangular shape anti-thrust with adductor padding SIZES: 11/12A/12P/13D/13S/14/15/16/17: US(30x38); XXS(36x38); XS(36x42); XS1(39x44); S(42x44); M(42x50);M1(45x50); L(48x44); XL(48x50)
	PMD 500-1B/2M/3D/4P/5N/6PR/7IM/8T-(Mis.)-101/201/501 - Versa Inserto seat Pelvis Positioning Systems TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 500: Versa Inserto Seat Pelvis Positioning Systems 1B: Inserto Seat Basico; 2M: Inserto Seat Mediano; 3D: Inserto Seat Domino; 4P: Inserto Seat Pucco with low backrest; 4PT: Inserto Seat Pucco with high backrest; 5N: Inserto Seat Nauco; 6PR: Inserto Seat Pratico; 7IM: Inserto Seat Impulso; 8T: Inserto Seat Tanto Mis.: size 101: incontinent cover; 201: air-exchange cover; 501: air/incontinent cover; 601: air/incontinent cover PU SIZES: 1B/2M/3D: UUS(25x30); USS(30x30); US(30x38); XXS(36x38); XS(36x42); XS1S(40x40); XS1(40x45); S(42x45); M(42x50); M1S(45x45); M1(45x50); L(48x45); XL(48x50) 4P: UUS(25x30); US(30x38) 5N: 22x25; 25x30; 30x34; 36x38; 40x42 6PR: 20x25; 25x25; 25x30; 30x30; 30x38; 36x38; 36x42; 40x40; 40x45; 42x45; 42x50; 45x45; 45x50; 48x45; 48x50 8T: US(30x38); XXS(36x38); XS(36x42); XS1S(40x40); XS1(40x45); S(42x45); M(42x50); M1S(45x45); M1(45x50); L(48x45); XL(48x50) 7IM: XS(36x42); XS1S(40x40); XS1(40x45); S(42x45); M1S(45x45); XL(48x50)
VERSA	PMD 500-1S/2S-(Mis.)- 501 - Versa Inserto Spine Pelvis Positioning System TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 500: Versa Inserto Seat Pelvis Positioning Systems 1S: Inserto Seat Modo; 2S: Inserto Seat Novo; 501: air/incontinent cover SIZES: 3638; 3642; 3840; 3845; 4040; 4045; 4242; 4245; 4250; 4545; 4550; 4848; 4850; 5050
	PMD 500-4PKL - Accessories for the Pelvis Positioning System Versa Inserto Seat Pucco TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 500: Versa Inserto Seat Pelvis Positioning Systems 4PKL: Leveling kit
VERSA	PMD 500-9MI-(Mis.)-101/301 - Versa Inserto Protection Cushion TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 500: Versa Inserto Seat Pelvis Positioning Systems 9MI: Inserto Protection Minimo Mis.: size 101: incontinent cover; 301: air-exchange cover SIZES: 9MI: XS(36x42); XS1S(40x40); XS1(40x45); S(42x45); M1S(45x45); XL(48x50)
	PMD 2 (Mis.) 11/12/21/22 - Trunk Positioning System - Versa TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 2: Versa Trunk Positioning System Mis.: size 11: rectangular shape flat padding; 12: rectangular shape contoured padding; 21: scapular cut-out shape and flat padding; 22: scapular cut-out shape and contoured padding SIZES: 11/12/21/22: US(30x38); XXS(36x38); XS(36x42); XS1(39x46); S(42x46); M(42x50);M1(45x52); L(48x50)
VERSA	PMD 501-1/2/3/4/5/6-(Mis.) - Trunk Positioning system Versa Inserto Back TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 501: Trunk Positioning System Versa Inserto Back 1: Supporto Back; 2: Effecto Lato; 3: Effecto Plus; 4: Facile; 5: Facile Basic; 6: Conco Mis.: size SIZES: 1: 30x33; 33x36; 36x40; 39x44; 42x48; 45x50; 48x52 2/3: 30x33; 33x38; 36x42; 39x45; 42x45; 42x50; 45x50; 48x55 4: 32x15; 32x21; 32x27; 36x18; 36x24; 36x30; 40x18; 40x24; 40x30; 44x18; 44x24; 44x30; 48x24; 48x30; 48x36 (the version without string is available for all measures, with simple strings (A) and the version with double string (B) excepted those 15 and 18 high. Code Example: PMD 501-4-4024; PMD 501-4-4024-A; PMD 501-4-4024-B) 5: 34x15; 34x21; 36x18; 36x24; 40x18; 40x24; 44x18; 44x24; 48x20; 48x26 6: 24x15; 24x21; 28x15; 28x21; 32x15; 32x21; 32x27; 36x18; 36x24; 36x30; 40x18; 40x24; 40x30 (the version without string is available for all measures, with simple strings (A) and the version with double string (B) excepted those 15 and 18 high. Code Example: PMD 501-6-4024; PMD 501-6-4024-A; PMD 501-6-4024-B)

<p style="text-align: center;">VERSA</p>	<p>PMD S/E 3/4 L/S D/S (Mis.) - Thoracic Supports for trunk positioning system Versa Inserto Back</p> <p>TECHNICAL FEATURES PMD: Pro Medicare S.r.l. S: Thoracic Support for Supporto Back; E: Thoracic Supporto for Effecto Back 3: Flat Pad ; 4: Contoured Pad L: Linear Pad ; S: Armpit cut Pad D/S: RH/LH Mis.: size SIZES: S-3: 1(6x6,5); 2(8x8,5); 3(10x10,5); 4(12x13,5); 5(12x16,5) S-4: 1(6x10,5); 2(8x12,5); 3(10x14,5); 4(12x17,5) E-3-L: 1(6x8); 2(8x10); 3(10x12); 4(12x15); 5(12x18) E-4-L: 1(8x12); 2(8x14); 3(10x16); 4(12x19) E-3-S: 1(8x10); 2(10x12); 3(12x15); 4(12x18) E-4-S: 1(8x14); 2(10x16); 3(12x19)</p>
<p style="text-align: center;">VERSA</p>	<p>PMD 3/4 (Mis.) D/S-1/2/3 A/B/C/D S - Thoracic Supports for trunk positioning system Versa</p> <p>TECHNICAL FEATURES PMD: Pro Medicare S.r.l. 3: Flat Pad ; 4: Contoured Pad Mis.: size D/S: RH/LH 1: Fixed bracket; 2: detachable bracket; 3: swing-away bracket A: L bracket; B: 2,5 cm offset bracket; C: 5 cm offset bracket; D: reverse bracket S: armpit cut SIZES: 3: XS(8x10); S(10x12); M(12x15); L(12x18) 4: XS(8x14); S(10x16); M(12x19)</p>
<p style="text-align: center;">VERSA</p>	<p>PMD 5/6 (Mis.) D/S-1/2 A/B/C/D - Hip Guides Versa</p> <p>TECHNICAL FEATURES PMD: Pro Medicare S.r.l. S: Linear hip guide; G: Contoured hip guide Mis.: size D/S: RH/LH 1: Fixed bracket; 2: detachable bracket; A: L bracket; B: 2,5 cm offset bracket; C: 5 cm offset bracket; D: reverse bracket SIZES: 5/6: XS(8x22); S(10x25); M(10x30); L(12x35)</p>
<p style="text-align: center;">VERSA</p>	<p>PMD 7/8 (Mis.) D/S P/A/PP/GP/PA/GA - Arm supports positioning system Versa</p> <p>TECHNICAL FEATURES PMD: Pro Medicare S.r.l. 7: Flat arm support; 8: Shaped arm support Mis.: size D/S: RH/LH P: flat w/standard brackets; A: contoured w/standard bracket; PP: palmar flat w/standard bracket; GP: elbow flat w/standard bracket; PA: palmar contoured w/standard bracket; GA: elbow contoured w/standard bracket SIZES: 7-P/A: XS(8x22); S(10x25); M(10x30); L(12x35) 8-PP/GP/PA/GA: XS(8x30x12); S(10x35x15); M(10x40x17); L(12x48x17)</p>
<p style="text-align: center;">VERSA</p>	<p>PMD 14/14R (Mis.) ()/R - Versa tray</p> <p>TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 14: Ergonomic wooden tray; 14R: Rectangular Tray Mis.: size (): without letter -> detachble R: lateral flip hardware SIZES: 14: US(47x58); P(53x69); M(58x75); G(66x86) 14R: US(45x56); P(50x66); M(55x71); G(63x82)</p>
<p style="text-align: center;">VERSA</p>	<p>PMD 14G/T ()/R (Mis.) - Versa gray tray/transparent</p> <p>TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 14: Tray G: gray T: transparent (): without letter -> detachble R: lateral flip hardware Mis.: size SIZES: US(45x56); P(50x66)</p>
<p style="text-align: center;">VERSA</p>	<p>PMD 14G-A ()/R (Mis.) - Versa gray tray/transparent for daily activities</p> <p>TECHNICAL FEATURES: PMD: Pro Medicare S.r.l. 14: Tray G: gray A: for daily activities (): without letter -> detachble R: lateral flip hardware Mis.: size SIZES: US; P</p>

VERSA	<p>PMD 13 (Mis.) - Abductor Wedge Versa</p> <p><u>TECHNICAL FEATURES:</u> PMD: Pro Medicare S.r.l. 13: Removable Abductor wedge Mis.: size <u>SIZES:</u> 13: S(7,5x9x7,5); M(9x10x9); L(10x11,5x10)</p>
VERSA	<p>PMD 18/19/25/26/16/17/21/15C (Mis.) - Positioning elements for Pelvis/Trunk/Inferior Limbs Versa Fixatis</p> <p><u>TECHNICAL FEATURES:</u> PMD: Pro Medicare S.r.l. 18: Dynamic Abduction harness; 19: Pelvic belt w/2 fixing points and 2 adjustments w/plastic buckle closure; 25: Pelvic belt w/4 fixing points and 2 adjustments w/metal closure; 26: Pelvic belt w/2 fixing points and 2 adjustments w/metal closure; 16: Dynamic butterfly harness; 17: Chest harness with shoulder retractor/stabilisation pads; 21: Trunk harness w/elastic shoulder retractors and chest buckle closure; 15C: Padded Mid-foot strap Mis.: Size <u>SIZES:</u> 18: S(28x41); M(33x49); L(38x55) 19: XS(4,5x12); S(5,5x17); M(7x22); L(7x27) 25/26: S(6x17); M(7x22); L(7x27) 16: XS(20x29); S(23x34); M(24x45); L(26x52) 17: S(16x18); M(18x20); L(23x23) 21: XS(4x25); S(4x35); M(6x40); L(6x45) 15C: S(18x5,5); M(22x7); L(27x10)</p>
VERSA	<p>PMD C01/C02 (Mis.) C - Head Positioning system Versa-Capitis</p> <p><u>TECHNICAL FEATURES:</u> PMD: Pro Medicare S.r.l. C01: Capitis confort with long horizontal bar; C02: Capitis anatomico with long horizontal bar Mis.: size C: with short horizontal bar <u>SIZES:</u> C01: P(21x14); M(30x14); G(42x16) C02: XP(18x13); P(24x17); M(28x19); G(32x25)</p>
VERSA	<p>PMD 15 D/S/15F/15V/15U/ (Mis.) - Elements for Footrests</p> <p><u>TECHNICAL FEATURES:</u> PMD: Pro Medicare S.r.l. 15 D/S: Separate Leg Cradle DX/SX 15F: Padded calf strap; 15V: Calf strap w/velcro; 15U: Calf Panel Mis.: size <u>SIZES:</u> 15 D/S: UUS (6x6); US(8,5x10); XXS(11,5x10,5); XS(11,5x12,5); XS0(12,5x15); XS1(12,5x15); S(14x15); M(14x17,5); M1(15x18); L(17,5x18); XL(17,5x18) 15F: US(11x26); XXS(11x31); XS(11x31); XS0 (11x34); XS1(11x34); S(13x37); M(13x37); M1(13x40); L(13x43); XL(13x43) 15V: US(4x25); XXS(4x30); XS(4x30); XS0(4x33); XS1(4x33); S(4x36); M(4x36); M1(4x39); L(4x42); XL(4x42) 15U: UUS(8x17); US(22x10); XXS(25x10,5); XS(25x12,5); XS0(26x15); XS1(26x15); S(28x15); M(29x17,5); M1(32x18); L(35x18) XL(35x18) D/S: DX/SX</p>
VERSA	<p>PMD 15FG/15VG - Elements for Footrests</p> <p><u>TECHNICAL FEATURES:</u> PMD: Pro Medicare S.r.l. 15FG: Padded calf strap gray; 15VG: calf strap w/velcro gray Mis.: size <u>SIZES:</u> 15FG: 1(10x20) 2(10x20); 3(10x26); 4(10x26); 5 (10x31); 6 (10x31); 7 (10x34) 15VG: 1(10x20) 2(10x20); 3(10x26); 4(10x26); 5 (10x31); 6 (10x31); 7 (10x34)</p>
VERSA	<p>D05-701-Y - Postural Back SENSO INPOCKET w/double and simple strings</p> <p>D05-704-Y - Postural Back FLEXIO</p> <p><u>TECHNICAL FEATURES:</u> D05: Versa range Y: size <u>SIZES:</u> 3630;3635;3640;4030;4035;4040;4430;4435;4440;4830;4835;4840</p>
VERSA	<p>D05-702-Y - Postural cushion SENSO COMPACTO</p> <p><u>TECHNICAL FEATURES:</u> D05: Versa range Y: size <u>SIZES:</u> 3638;3642;3840;3845;4040;4045;4242;4245;4250;4545;4550;4848;4850;5050</p>
VERSA	<p>D05-703-Y - Postural cushion FLEXIO PLUS</p> <p><u>TECHNICAL FEATURES:</u> D05: Versa range Y: size <u>SIZES:</u> 3638;3642;3840;3845;4040;4045;4242;4245;4250;4545;4550;4848;4850;5050</p>
VERSA	<p>D05-705-Y - Inserto Seat Vip Pelvis Positioning System</p> <p><u>TECHNICAL FEATURES:</u> D05: Versa range Y: size <u>SIZES:</u> 3232;3236;3434;3438;3638;3642;3840;3845;4040;4045;4242;4245;4250;4545;4550;4848;4850;5050</p>

VERSA	D05-706-Y - Inserto Back Vip Trunk Positioning System w/double strings
	D05-707-Y - Inserto Back Vip Trunk Positioning System
VERSA	<u>TECHNICAL FEATURES:</u> D05: Versa range Y: size <u>SIZES:</u> 3630;3635;3640;4030;4035;4040;4430;4435;4440;4830;4835;4840
	PMD C01/C02 (Mis.) B - Head Positioning system Versa-Capitis w/brackets <u>CARATTERISTICHE:</u> PMD: Pro Medicare S.r.l. C01: Capitis confort; C02: Capitis anatomico Mis.: size B: bracket <u>SIZES:</u> C01: P(21x14); M(30x14); G(42x16) C02: XP(18x13); P(24x17); M(28x19); G(32x25)
VERSA	PMD 14R(Mis.)DP - Versa tray detachable <u>CARATTERISTICHE:</u> PMD: Pro Medicare S.r.l. 14R: Rectangular tray Mis.: size DP: double hardware <u>SIZES:</u> 14R: US(45x56); P(50x66); M(55x71); G(63x82)

NOTE: All sizes are expressed in centimeters (cm)