











- TECHNICAL SHEET -
“MULTISOFT” Positioning Devices

<u>Manufacturer identification</u>	<p>Pro Medicare s.r.l. Via Montagna Z.I. Lotto 41 72023 Mesagne (Br) VAT Number 01803920741 tel. 00 39 0831 777840 fax 00 39 0831 730739 website: www.promedicare.eu e-mail: info@promedicare.it</p>
<u>Device Commercial Name</u>	MULTISOFT Range – ROTOLINO/SAGAR/TACT/SUNICO Models
<u>UDI-DI BASIC</u>	805571347SOLLIEVO8
<u>Device Code</u>	<p>ROTOLINO: D09-001-1 SAGAR height 17: D00-022-1/2/3/4 SAGAR height 27: D00-023-1/2/3/4 SAGAR height 37: D00-024-1/2/3/4 TACT A: D00-025-X TACT B: D00-026-X SUNICO: D00-038-X</p>
<u>Code of Classification (CND)</u>	V080302
<u>Medical Device Class</u>	<i>These Devices are CE marked according to EU Regulation 2017/745 and they are classified as non sterile Class I Medical Devices without measuring function.</i>
<u>Intended use</u>	<p>SAGAR/ROTOLINO/SUNICO are devices for positioning and/or containment of the posture of a body segment or of the whole body following a temporary or permanent pathological condition and/or during clinical/surgical treatment. TACT is the device for positioning and/or containment of the posture of the hand following a temporary or permanent pathological condition and/or during clinical/surgical treatment. Their intended use is to:</p> <ul style="list-style-type: none"> - treat postural disorders; - provide a suitable and fully comfortable positioning of the user or one of his/her body segments; - ensure the containment of a user's body; - support during Pressure Ulcers Treatment; - facilitate the distribution of body pressures. <p>Positioning devices are for paediatric and adult users and are intended for professional and also for non-professional use in order to relieve and/or prevent clinical pathological conditions related to posture or post-traumatic, surgical and post-surgical conditions as well as for rehabilitation; such devices must be used in internal spaces. Multisoft devices do not have load-bearing structural features, so they do not replace the user's support (bed/mattress)</p>
<u>Technical features</u>	<p>STANDARD CONFIGURATION: Each model and size chosen include the padded and covered element, the removable cover is with anti-slip bottom surface (SUNICO is not available with anti-slip bottom surface).</p> <p>DIMENSIONS: Different for each model as shown by tables below</p> <p>WEIGHT: Multisoft ROTOLINO < 500 gr Multisoft SAGAR < 1.2 kg Multisoft TACT A/B < 100 gr SUNICO < 6 kg</p>

Technical features																			
	ROTOLINO Model	SAGAR Model	TACT A Model	TACT B Model	SUNICO Model														
	<p style="text-align: center;">One Size</p> <p>length: 140 cm</p> <p>central part diameter: 13 cm</p> <p>two sides/ends diameter: 10 cm</p>	<table border="1"> <tr> <td rowspan="4" style="text-align: center;">L x H (cm) (H = 17 cm)</td> <td style="text-align: center;">Size 1 (47x17)</td> </tr> <tr> <td style="text-align: center;">Size 2 (57x17)</td> </tr> <tr> <td style="text-align: center;">Size 3 (67x17)</td> </tr> <tr> <td style="text-align: center;">Size 4 (77x17)</td> </tr> <tr> <td rowspan="4" style="text-align: center;">L x H (cm) (H = 27 cm)</td> <td style="text-align: center;">Size 1 (47x27)</td> </tr> <tr> <td style="text-align: center;">Size 2 (57x27)</td> </tr> <tr> <td style="text-align: center;">Size 3 (67x27)</td> </tr> <tr> <td style="text-align: center;">Size 4 (77x27)</td> </tr> <tr> <td rowspan="4" style="text-align: center;">L x H (cm) (H = 37 cm)</td> <td style="text-align: center;">Size 1 (47x37)</td> </tr> <tr> <td style="text-align: center;">Size 2 (57x37)</td> </tr> <tr> <td style="text-align: center;">Size 3 (67x37)</td> </tr> <tr> <td style="text-align: center;">Size 4 (77x37)</td> </tr> </table>	L x H (cm) (H = 17 cm)	Size 1 (47x17)	Size 2 (57x17)	Size 3 (67x17)	Size 4 (77x17)	L x H (cm) (H = 27 cm)	Size 1 (47x27)	Size 2 (57x27)	Size 3 (67x27)	Size 4 (77x27)	L x H (cm) (H = 37 cm)	Size 1 (47x37)	Size 2 (57x37)	Size 3 (67x37)	Size 4 (77x37)	<p style="text-align: center;">Size 1 diameter: 13cm</p> <p style="text-align: center;">Size 2 diameter: 15cm</p>	<p style="text-align: center;">Size 1 L x H (cm) 15x7</p> <p style="text-align: center;">Size 2 L x H (cm) 15x9</p>
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<p>PERFORMANCE AND DURABILITY: The realistic life span of these devices is 2 years (padding) valid under normal conditions of use and proper maintenance in accordance with the specifications of the instruction manual.</p>																			
Technical features	<p>MATERIALS: The padded elements are made of high performance materials used in the medical sector:</p> <ol style="list-style-type: none"> 1. Padded elements are made of polymer foams filling cuttings; 2. The interior and removable covers are made of PU/PES combined materials with the following characteristics: <ul style="list-style-type: none"> - antibacterial according to the standard ISO 20743-2 (Staphylococcus aureus, Methicilin Resistan Staphylococcus Aureus MRSA) - non cytotoxic according to the standard ISO 10993-5 and ISO 10993-12 - non irritating according to the standard ISO 10993-10 and ISO 10993-1 - resistant to virus penetration according to the standard ISO 16604 - antifungal according to ASTM G 21-96 - fireproof according to the standard BS 7175; crib 5 - biocompatible according to the standard ISO 10993 - OEKO-TEX® - Latex free - breathable according to the standard ISO 15496 - waterproof according to the standard EN 20811 <p>MANTEINANCE AND CLEANING: The internal and the removable covers can be superficially sanitized with the following detergents/disinfectants:</p> <ul style="list-style-type: none"> • PERSIL EXPERT coldzyme/HENKEL • 70% etanol • PERFORM/Schuelke • TPH PROTECT/Schuelke • MIKROZID AF liquid/Oktal pharma • DESCOGEN liquid/Antiseptica • MANORAPID/Antiseptica • PLIVASEPT/Pliva • INCIDIN PLUS/Ecolab <p>The removable cover can be washed at high temperatures (95° max 10 washings or dry), can be sterilized at 134°/5 min (10 times maximum).</p> <p><u>Do not use cleaners based on natrium hipo-chlorite for both cover.</u></p> <p>PACKAGING: It is supplied in a plastic bag</p>																		

Spare Parts	<i>Additional Covers</i>
Additional Elements	<ul style="list-style-type: none"> - Mobile station with complete element kit and additional covers (to be configured according to needs) - Bag for a set of elements (to be configured according to needs)
Product image <i>(images are purely illustrative)</i>	 <u>ROTOLINO Model</u>
	 <u>SAGAR Model</u>
	 <u>TACT A Model</u>
	 <u>TACT B Model</u>
	 <u>SUNICO Model</u>