





## SENSO COMPACTO Positioning Cushion Technical Sheet

<b><u>Manufacturer identification</u></b>	Pro Medicare s.r.l. Via Montagna Z.I. Lotto 41 72023 Mesagne (Br) P.IVA 01803920741 tel. 00 39 0831 777840 sito web: <a href="http://www.promedicare.eu">www.promedicare.eu</a> e-mail: <a href="mailto:info@promedicare.it">info@promedicare.it</a>								
<b><u>Device Commercial Name</u></b>	SENSO COMPACTO								
<b><u>UDI-DI BASIC</u></b>	805660010POSTURAVERSAS3								
<b><u>Device code</u></b>	<p><b>D05-702-X</b> refers to <u>h=7 cm</u> (where X refers to the size: X=1-&gt; refers to size 3638; X=2-&gt; size 3642; X=3-&gt; size 3840; X=4-&gt; size 3845; X=5-&gt; size 4040; X=6-&gt; size 4045; X=7-&gt; size 4242; X=8-&gt; size 4245; X=9-&gt; size 4250; X=10-&gt; size 4545, X=11-&gt; size 4550, X=12-&gt; size 4848, X=13-&gt; size 4850, X=14-&gt; size 5050).</p> <p><b>D05-708-X</b> refers to <u>h=9 cm</u> (where X refers to the size: X=1-&gt; refers to size 3638; X=2-&gt; size 3642; X=3-&gt; size 3840; X=4-&gt; size 3845; X=5-&gt; size 4040; X=6-&gt; size 4045; X=7-&gt; size 4242; X=8-&gt; size 4245; X=9-&gt; size 4250; X=10-&gt; size 4545, X=11-&gt; size 4550, X=12-&gt; size 4848, X=13-&gt; size 4850, X=14-&gt; size 5050).</p> <p>The SENSO COMPACTO cushion, both in the 7 cm and 9 cm heights, features black zippers and the “standard” cover for the modular elements.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td rowspan="3" style="text-align: center; vertical-align: middle;">Variant codes::</td> <td rowspan="3" style="text-align: center; vertical-align: middle;">Zippers colors</td> <td style="text-align: center;">OPT D05-702-APPLE</td> </tr> <tr> <td style="text-align: center;">OPT D05-702-ORCHID</td> </tr> <tr> <td style="text-align: center;">OPT D05-702-TIFFANY</td> </tr> <tr> <td></td> <td style="text-align: center; vertical-align: middle;">“Shape” cover for the modular elements</td> <td style="text-align: center;">OPT D05-702-SHAPE</td> </tr> </table>	Variant codes::	Zippers colors	OPT D05-702-APPLE	OPT D05-702-ORCHID	OPT D05-702-TIFFANY		“Shape” cover for the modular elements	OPT D05-702-SHAPE
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<b><u>Code of Classification (CND)</u></b>	<b>Y1809</b>								
<b><u>Medical Device Class</u></b>	SENSO COMPACTO Positioning cushion is CE marked according to EU Regulation 2017/745 and it is a non sterile Class I Medical Device.								
<b><u>Intended use</u></b>	<p>The modular postural cushion for wheelchair users consisting of:</p> <ul style="list-style-type: none"> <li>- a flexible base with reinforcing elements inside and equipped with fastening systems (hook-and-loop fasteners)</li> <li>- two padded and covered modular elements, equipped with fastening systems (hook-and-loop fasteners) with inside, a series of inserts with various shapes designed to accommodate and/or follow the shape of the user’s pelvis</li> <li>- a kit of long triangular-shaped inserts</li> <li>- a kit of short triangular-shaped inserts.</li> </ul> <p>The SENSO COMPACTO cushion switches from an unfolded use configuration to a folded non-use configuration without having to be removed from the wheelchair. It is made from materials appropriately validated and tested to ensure lightness, comfort, and long-term durability, and it is also designed and manufactured in compliance with safety standards as required by the relevant Regulation (EU) 2017/745.</p> <p>Its intended use is to:</p> <ul style="list-style-type: none"> <li>- manage postural disorders;</li> <li>- promote adequate positioning and support of the user’s pelvis;</li> <li>- assist in the redistribution of body pressure;</li> <li>- relieve and ventilate all bony prominences and the genital area;</li> <li>- compensating/supporting/aligning mild pelvic misalignments.</li> </ul> <p>The SENSO COMPACTO Positioning System in the “7 cm height” version, is intended for users at low/moderate risk of developing pressure injuries; The “9 cm height” version is intended for users at high risk of pressure injury development. Areas with no contact and therefore without pressure can assist in the healing process and support the treatment of existing pressure ulcers.</p>								
<b><u>Technical features</u></b>	<p><b>STANDARD CONFIGURATION:</b> the cushion comes complete with a flexible base element with reinforcing elements, two padded and covered modular elements (optionally, the cover may have a different shape), with inside a series of inserts with various shapes designed to accommodate and/or follow the shape of the user’s pelvis.</p> <p><b>DIMENSIONS:</b> available in 14 sizes, each of which can be adjusted by 2 cm in width</p>								

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	<p><b>WEIGHT:</b> &lt; 1.8 kg</p>																																																		
<b>Technical features</b>	<p><b>MAX LOAD:</b> 136 kg/300 lb</p> <p><b>PERFORMANCE AND DURABILITY:</b> The expected duration of safe and effective performance of the devices is 2 years (padding) valid under normal conditions of use and proper maintenance in accordance with the specifications of the instruction manual.</p> <p><b>MATERIALS:</b> It is made of high-performance materials widely used in the medical industry:</p> <ol style="list-style-type: none"> <li>the paddings made of polyurethane foam of different density, bearing capacity and shape memory;</li> <li>Covers and the flexible base are made of PU/PES combined materials with the following characteristics: <ul style="list-style-type: none"> <li>- antibacterial</li> <li>- non citotoxic</li> <li>- non irritating</li> <li>- resistant to virus penetration</li> <li>- antifungal</li> <li>- fireproof</li> <li>- biocompatible</li> <li>- OEKO-TEX®</li> <li>- Latex free</li> <li>- breathable</li> <li>- waterproof</li> </ul> </li> <li>The inserts are made of soft-density polyethylene material</li> </ol> <p><b>MANTEINANCE AND CLEANING:</b> The removable cover can be washed at high temperatures 60° and sanitized with the following detergents/disinfectants:</p> <ul style="list-style-type: none"> <li>• PERSIL EXPERT coldzyme/HENKEL</li> <li>• 70% etanol</li> <li>• PERFORM/Schuelke</li> <li>• TPH PROTECT/Schuelke</li> <li>• MIKROZID AF liquid/Oktal pharma</li> <li>• DESCOGEN liquid/Antiseptica</li> <li>• MANORAPID/Antiseptica</li> <li>• PLIVASEPT/Pliva</li> <li>• INCIDIN PLUS/Ecolab</li> </ul> <p>Non usare detergenti a base di ipoclorito di sodio, do not spin-dry. Do not wash the structural parts; the padding covers can be superficially sanitized with the products listed above.</p> <div style="text-align: center;">     </div> <p><b>PACKAGING:</b> Supplied inside a catron box</p>																																																		

**Product image**  
*(images are purely illustrative)*



Variant with "standard" cover for the modular elements



Variant with "shape" cover for the modular elements

