

- The Wheelchair Cover for Infection Prevention and Contagion Containment-

<u>Manufacturer Identification</u>	Pro Medicare s.r.l. Via Montagna Z.I. Lotto 41 72023 Mesagne (Br)
<u>Device Commercial Name</u>	<i>The Wheelchair Cover for Infection Prevention and Contagion Containment</i>
<u>Intended Use</u>	<p><i>The Device covers the surface of Transport Wheelchair and Wheelchair for Disabled people, it has been designed to maintain the surface integrity and avoid the contact of the same surface between the different users; it is a protective physical barrier designed to provide the contagion containment which is caused by the contact with infected surfaces.</i></p> <p><i>The Device is intended to be used by any person "user" only after reading the the instruction of use and any restrictions.</i></p>
<u>Device Code</u>	D01-001-1
<u>Code of Classification (CND)</u>	T030104
<u>Main Features</u>	<p><i>The Device has been designed to cover Wheelchairs of various types (es. Standard/folding/Tilting/Powered Wheelchair and Wheelchair with Positioning System, ecc...); The backside of the cover presents a cut to facilitate the insertion on the wheelchair (when it is in combination with the Headrest).</i></p> <p><i>The cover is made of PU/PES combined materials with the following characteristics:</i></p> <ul style="list-style-type: none"> - <i>antibacterial according to the standard ISO 20743-2 (Staphylococcus aureus, Methicilin Resistan Staphylococcus Aereus MRSA)</i> - <i>non cytotoxic according to the standard ISO 10993-5 and ISO 10993-12</i> - <i>non irritating according to the standard ISO 10993-10 and ISO 10993-1</i> - <i>resistant to virus penetration according to the standard ISO 16604</i> - <i>antifungal according to ASTM G 21-96</i> - <i>fireproof according to the standard BS 7175; crib 5</i> - <i>biocompatible according to the standard ISO 10993</i> - <i>OEKO-TEX®</i> - <i>latex free</i> - <i>breathable according to the standard ISO 15496</i> - <i>waterproof according to the standard EN 20811</i> <p><i>The cover can be washed at high temperatures (95°/10 washing maximum or dry clean), can be sterilized in autoclave at 134°/5 min (10 times maximum) and sanitized with the following detergents/ disinfectants:</i></p> <ul style="list-style-type: none"> - <i>PERSIL EXPERT coldzyme / HENKEL</i> - <i>70% etanol</i> - <i>PERFORM / Schuelke</i> - <i>TPH PROTECT / Schuelke</i> - <i>MIKROZID AF liquid / Oktal pharma</i> - <i>INCIDIN PLUS / Ecolab</i> - <i>DESCOGEN liquid / Antiseptica</i> - <i>MANORAPID / Antiseptica</i> - <i>PLIVASEPT / Pliva</i> - <u>Sodium hypochlorite-based products cannot be used</u>

	 <p>The Device is CE marked according to EU Regulation 2017/745 and it is a non sterile Class I Medical Device without a measuring function.</p>
<p><u>Packaging</u></p>	<p>The Device is packed individually in pouch.</p>
<p><u>Product Image</u> (The images are purely illustrative)</p>	
<p><u>Weight and Dimensions</u></p>	<p>The cover has a total weight of 100 g. and it covers wheelchair which have maximum width of 60 cm and maximum seat+backrest length of 120 cm.</p>