

PROX Modular Cushion Technical Sheet

<p><u>Manufacturer identification</u></p>	<p>Pro Medicare s.r.l. Via Montagna Z.I. Lotto 41 72023 Mesagne (Br) P.IVA 01803920741 tel. 00 39 0831 777840 website: www.promedicare.eu e-mail: info@promedicare.it</p>
<p><u>Device Commercial Name</u></p>	<p>PROX Modular Cushion</p>
<p><u>Device Code</u></p>	<p>D00-008-1</p>
<p><u>Code of Classification (CND)</u></p>	<p>V080302</p>
<p><u>Medical Device Class</u></p>	<p>Prox is CE marked according to EU Regulation 2017/745 and it is a non sterile Class I Medical Device.</p>
<p><u>Intended Use</u></p>	<p><i>PROX is the modular and adjustable cushion equipped with gripping systems; its flexible support base also equipped with reinforcing elements allows to be used on any type of seat (e.g. chair, armchair, seat, wheelchair) with a width of not less than 38 cm, switching from an extended to a folded non-use configuration by avoiding the repositioning of the modular elements provided.</i></p> <p><i>Its intended use is aimed to adjust the position of the pelvis in situations where it is necessary to relieve and ventilate the medial buttock, coccygeal, sacral, perineal and genital areas of the seated person and only the lateral components, in the posterior part keep the central area of the pelvis unloaded and not overloaded.</i></p> <p><i>Gripping systems allow to adjust the width and length of the cushion by a few centimeters in both reduction and extension to adapt it to the anthropometric measurements of the adolescent and/or adult user. In addition, it is possible to adjust the sinking of the part to be unloaded and/or ventilated.</i></p>
<p><u>Technical features</u></p>	<p>DIMENSION: length x width: 40x43 [cm]/15,5"x17"</p> <p>WEIGHT: <1 kg</p> <p>MAXIMUM LOAD: 100 kg/220 lb</p> <p>PROX cushion includes:</p> <ul style="list-style-type: none"> - a flexible support base with reinforcing elements inside; gripping systems and handles; - 3 padded and upholstered modular elements; - accessories (if ordered) (e.g carrying bag). <p>PERFORMANCE AND DURABILITY: If used in safe conditions, its performances and durability is 2 years (padding); it is valid under normal conditions of use and proper maintenance as specified in the instruction manual.</p> <p>MATERIALS: it is made of high-performance materials used in the medical industry;</p> <ul style="list-style-type: none"> - Reinforcing elements and inserts are made of soft density polyethylene foam; - the paddings made of polyurethane foam of different density, bearing capacity and shape memory;

	<ul style="list-style-type: none"> - 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 Staphylocococ Aereus 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 removable cover can be washed at high temperatures (95°/10 washing maximum or dry clean), can be sterilized at 134°/5 min (10 times maximum) and 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>SODIUM HYPOCHLORITE-BASED PRODUCTS CANNOT BE USED</p> <p>PACKAGING: It is supplied in a plastic bag and it is packed in carton.</p>
<p>Accessories</p>	<p>Portable bag</p>
<p>Product image (images are purely illustrative)</p>	