

- TECHNICAL SHEET -

XER Range Head Support and containment systems in lying and reclining positions

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| <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 fax 00 39 0831 730739 Website: www.promedicare.eu e-mail: info@promedicare.it</p> | |
| <p><u>Device Commercial Name</u></p> | <p>XER RANGE – CORONĂ/ANGELÛS/STILLA A/STILLA B/NUBES A/NUBES B Models</p> | |
| <p><u>UDI-DI BASIC</u></p> | <p>805571347SOLLIEVO8</p> | |
| <p><u>Device Code</u></p> | <p>XER Type “A” with anti-slip material bottom surface as a continuous and distributed gripping system, available in different sizes (X):</p> <p>D00-010-X (CORONĂ model) D00-012-X (ANGELÛS model) D00-014-X (STILLA A model) D00-016-X (STILLA B model) D00-018-X (NUBES A model) D00-020-X (NUBES B model)</p> | <p>XER Type “B” with bottom surface equipped with male fastening system, available in different sizes (X):</p> <p>D00-011-X (CORONĂ model) D00-013-X (ANGELÛS model) D00-015-X (STILLA A model) D00-017-X (STILLA B model) D00-019-X (NUBES A model) D00-021-X (NUBES B model)</p> |
| <p><u>Code of Classification (CND)</u></p> | <p>V080302</p> | |
| <p><u>Medical Device Class</u></p> | <p><i>The devices are CE-marked according to EU Regulation 2017/745 and are classified as non-sterile class I medical devices without a measuring function.</i></p> | |
| <p><u>Intended use</u></p> | <p><i>The head support and containment systems are paediatric and adult devices to be used for the postural treatment of the head in lying and reclining positions; their intended use is to relieve and ventilate particular areas of the head, to allow the head pressure distribution and to define the proper alignment of the head-neck segment also using (if needed and chosen) various types of leveling/slant wedges; it is advisable to always ensure the compatibility and stability of the device with the relative support base. The Devices are intended for professional and also for non-professional use in order to relieve clinical pathological conditions related to posture or post-traumatic conditions as well as for rehabilitation; such devices must be used in internal spaces. If Xer Type A device is used without the accessory cover, its use is considered to be for a single patient until deterioration. If Xer Type B device is used, accessory covers are mandatory to be used. The device materials have been appropriately validated and tested to ensure lightness, comfort and long lasting performance, and are also designed and manufactured in compliance with safety regulations as resulting from the relevant Regulation (EU) 2017/745. For a complete list of optional parts and/or accessories, please refer to the latest order form.</i></p> | |

STANDARD CONFIGURATION: Variable section tubular shape padded element in the model and type chosen

DIMENSIONS: each padded element comes in the following sizes

| DIMENSIONS (HxW) cm | | | | | | | | | | | | |
|---------------------|--------|----------------------|--------|-----------------------|--------|-----------------------|--------|----------------------|--------|----------------------|--------|-----------|
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| CORONA Model | | ANGELUS Model | | STILLA A Model | | STILLA B Model | | NUBES A Model | | NUBES B Model | | |
| TYPE "A" | Size 1 | 21x9 | Size 1 | 22x11 | Size 1 | 15x9 | Size 1 | 15x9 | Size 1 | 11.5x15.5 | Size 1 | 11.5x15.5 |
| | Size 2 | 28x13 | Size 2 | 29x13 | Size 2 | 20x12 | Size 2 | 20x12 | Size 2 | 15x18.5 | Size 2 | 15x18.5 |
| | Size 3 | 40x18 | Size 3 | 42x22 | Size 3 | 29x17 | Size 3 | 29x17 | Size 3 | 21x28 | Size 3 | 21x28 |
| TYPE "B" | Size 0 | 17x6 | Size 0 | 18x9 | Size 1 | 15x9 | Size 1 | 15x9 | Size 1 | 11.5x15.5 | Size 1 | 11.5x15.5 |
| | Size 1 | 21x9 | Size 1 | 22x11 | Size 2 | 20x12 | Size 2 | 20x12 | Size 2 | 15x18.5 | Size 2 | 15x18.5 |
| | Size 2 | 28x13 | Size 2 | 29x13 | Size 3 | 29x17 | Size 3 | 29x17 | Size 3 | 21x28 | Size 3 | 21x28 |
| | Size 3 | 40x18 | Size 3 | 42x22 | | | | | | | | |

WEIGHT: under 300 g

PERFORMANCE AND DURABILITY: The realistic lifespan 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.

MATERIALS: The padded elements come in high performance materials used in the medical sector:

- Padded elements are made of polymer foams filling elements (cutouts and reinforcement elements) of different densities and stiffnesses;
- The cover (with or without male fastening systems) are equipped with internal pockets to insert rigid elements and external pockets to insert elements to adjust the direction. The cover of each padded element is made of PU/PES combined material with the following characteristics:
 - antibacterial according to the standard ISO 20743-2 (Staphylococcus aureus, Methicilin Resistan Staphylococcus 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

CLEANING AND MAINTENANCE: The surface of the padded element upholstery can be sanitised only with detergents/disinfectants listed below:

- 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

Do not use cleaners based on natrium hipo-chlorite.

PACKAGING: packed individually in envelope

Technical features

Accessories

FLEXIBLE MATS made of PU/PES combined material (for material characteristics see padded element covers) and polymer foams:

- **Mat** anti-slip bottom and top surface as a continuous and distributed gripping system - compatible only with Xer Type A - its use is considered to be for a single patient until deterioration.

Code: C00-00038-X (various sizes)

- **Mat** with top surface provided with discrete gripping system (female fastening straps), anti-slip bottom surface as a continuous and distributed gripping system - compatible only with Xer Type B

Code: C00-00039-X (various sizes)

- **Mat** with top surface provided with discrete gripping system (female fastening straps), anti-slip bottom surface as a continuous and distributed gripping system and pockets to insert leveling wedges – compatible only with Xer Type B in Size 0

Code: C00-00070-0

- **Mat** with top surface provided with discrete gripping system (female fastening straps), anti-slip bottom surface as a continuous and distributed gripping system and pockets in the middle to insert leveling wedges – compatible only with Xer Type B

Code.: C00-00040-X (only Sizes 1, 2, 3)

CLEANING AND MAINTENANCE same as padded elements

PACKAGING: packed individually in envelope

SLANT AND LEVELING WEDGES made of PU/PES combined material (for material characteristics see padded element covers) and polymer foams:

- **Slant wedges** to adjust the direction of the tubular padded elements

Code: C00-00041-X (various sizes)

- **Posterior leveling wedge** for mat – compatible only with mat with pockets

Code: C00-00042-X (various sizes)

- **Lateral leveling wedge** for mat – compatible only with mat with pockets

Code: C00-00043-X (various sizes)

- **Lateral and posterior supporting wedge** in memory foam - compatible only with Xer Type B in Size 0

Code: C00-00071-0

CLEANING AND MAINTENANCE same as padded elements

PACKAGING: packed individually in envelope

COVERS made of PU/PES combined material (for material characteristics see padded element covers) with anti-slip material bottom surface as a continuous and distributed gripping system:

- Pocket shaped cover for CORONĂ/ANGELŪS/STILLA A/STILLA B/NUBES A/NUBES B models in Type A

Code: A00-00051-X/A00-00052-X/A00-00053-X/A00-00054-X/A00-00055-X/A00-00056-X (various sizes)

- Zippered cover for CORONĂ/ANGELŪS models in Type B Size 0

Code: A00-00097-0

- Pocket shaped cover for the Type B combination of one or more models CORONĂ/ANGELŪS/STILLA A/STILLA B/NUBES A/NUBES B together with mats compatible with Xer Type B.

A00-00057-X (only Sizes 1, 2, 3)

CLEANING AND MAINTENANCE:

The removable covers can be washed at high temperatures (90° max 10 washings or dry), can be sterilized at 134°/5 min (10 times maximum) and the surface can also be sanitized with the following detergents/disinfectants: PERSIL EXPERT coldzyme/HENKE, 70% etanol, PERFORM/Schuelke, TPH PROTECT/Schuelke, MIKROZID AF liquid/Oktal pharma, DESCOGEN liquid/Antiseptica, MANORAPID/Antiseptica, PLIVASEPT/Pliva, INCIDIN PLUS/Ecolab.

Do not use cleaners based on natrium hipo-chlorite.

PACKAGING: packed individually in envelope

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| <p><u>ADDITIONAL ELEMENTS</u></p> | <ul style="list-style-type: none"> - <u>Mobile station with the complete kit of elements and many accessories</u> - <u>Bag with pockets</u> for elements in size 0 - <u>Bag with pockets</u> for elements in size 1/2 - <u>Bag with pockets</u> for elements in size 3 - <u>Bag with pockets</u> for elements in sizes 1/2 and 2/3 - <u>complete elements and accessories kit</u> with bag with pockets |
| <p><u>Product Images</u> <i>(Images are purely illustrative)</i></p> | <div style="display: flex; flex-wrap: wrap; justify-content: space-around; text-align: center;"> <div style="width: 45%;">  <p><u>CORONĂ Model</u></p> </div> <div style="width: 45%;">  <p><u>ANGELŪS Model</u></p> </div> <div style="width: 45%;">  <p><u>STILLA A Model</u></p> </div> <div style="width: 45%;">  <p><u>STILLA B Model</u></p> </div> <div style="width: 45%;">  <p><u>NUBES A Model</u></p> </div> <div style="width: 45%;">  <p><u>NUBES B Model</u></p> </div> </div> |