



**Description:** Synthetic orthopaedic padding

<b>Final dimensions:</b>	2.7 m x7.5 cm
<b>Composition:</b>	Polyester.
<b>Construction:</b>	Synthetic/Sintética
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>Sterilizable by:</b>	Ethylene Oxide
<b>Width variation:</b>	± 7,5 mm
<b>Length variation:</b>	± 135 mm
<b>Colour:</b>	white
<b>Shelf life:</b>	120 months
<b>CFU/g</b>	<10 <sup>2</sup>
<b>Fluorescence</b>	conform



<b>Nr and Revision Date:</b>	16 -- 1997/01/07
<b>CE Class:</b>	I
<b>CE mark:</b>	CE
<b>Directive:</b>	MDD 93/42/EEC amended by 2007/47/EC

<b>Applicable norms:</b>	EN ISO 13485:2016 ; EN 1041+A1:2013 ; EN ISO 11737-1:2006 ; EN 1041:2008 ; ENISO11737-1:2006/AC:2009 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ;
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**Important Notes:** Rolls individually wrapped in paper band and cellophane

Level	Type	Dimension	Stamp	Labels
1	1 Printed cellophane		stamped	
2	144 Carton box	384x384x311mm		labeled

**Important Notes:** Nr pcs/pack subjected to ± 3% variation

<b>Storage instructions</b>	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply
<b>Waste instructions</b>	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
<b>Intended use</b>	For orthopaedic cushioning. Easy to cut and tear. High conformability. Thick and dense for maximum comfort. Economic model. Specially indicated for short term immobilization.

<b>WASTE AND ENVIRONMENT REGULATIONS</b>	Weight (gr) of packing material used in 100 pcs	341
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**ISSUED BY:** Quality Management Department, 2019/08/07