



Description: Synthetic orthopaedic padding

Final dimensions:	2.7 m x5 cm
Composition:	Polyester.
Construction:	Synthetic/Sintética
Latex:	Free
PVC:	Free
Re use:	No
Sterilizable by:	Ethylene Oxide
Width variation:	± 5 mm
Length variation:	± 135 mm
Colour:	white
Shelf life:	120 months
CFU/g	<10 ²
Fluorescence	conform



Nr and Revision Date:	13 -- 1997/01/07
CE Class:	I
CE mark:	CE
Directive:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	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	216 Carton box	384x384x311mm		labeled

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

Storage instructions	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
Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	For orthopaedic cushioning. Easy to cut and tear. High conformability. Thick and dense for maximum comfort. Economic model. Specially indicated for short term immobilization.

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	227
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ISSUED BY: Quality Management Department, 2019/08/07