

Ref: 420-002

Technical Specifications

Brand:



Description: Synthetic orthopaedic padding

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

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Nr and Revision Date:	16 1997/01/07
CE Class:	I
CE mark:	CE
Directive:	MDD 93/42/EEC amended by 2007/47/EC
Applicable perma	ENLICO 40405,0040 - EN 4044 - A4,0040 - EN

 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 ;

Important Notes: Rolls individually wrapped in paper band and cellophane

Level		Туре	Dimension		Stamp	Labels
1	1	Printed cellophane			stamped	
2	144	Carton box	384x384x311r	nm		labeled

Important Notes:	Nr pcs/pack subjected to ± 3% variation			
	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and			
Storage instructions	therefore,normal conditions of medical devices storage shall apply			
	No special requirements. The waste must be disposed according to local legal regulations for the			
Waste instructions	disposable of medical waste.			
	For orthopaedic cushioning. Easy to cut and tear. High conformability. Thick and dense for maximum			
Intended use	comfort. Economic model. Specially indicated for short term immobilization.			

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	341

ISSUED BY: Quality Management Department, 2019/08/07

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