


Description: Orthopaedic padding Synthetic

Final dimensions:	2.7 m x10 cm
Composition:	Polyester.
Construction:	Synthetic/Sintética
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Width variation:	± 10 mm
Length variation:	±135 mm
Colour:	white
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_SAL	≤10 ⁻⁶
Weigh/sqm	80 ± 10% g/m ²
Dry Elongation at breakMD	<400 %
Dry Tensile strength MD	1,5-13 N/5cm
Note	Tearable by hand
Air Permeability	>180 l/min/100cm ²

STERILE EO


isento
Latex
free

isento
PVC
free


Nr and Revision Date:	35 -- 2023/06/06
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	EN 17141:2020 ; ISO 14644-2:2015 ; ISO 14644-3:2019 ; ISO 8601-1:2019 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; ISO 10993-7:2008 Amd1 2019 ; ISO 10993-18:2020 AMD1:2022 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; ASTM F1980 16 ; ISO 14644-1:2015 ; ISO 14644-5:2004 ; ISTA Standard 2A ; ASTM D4169-22 ; ASTM D7386-16 ; ISO 2759:2014 ; ISO 3037:2013 ; EN ISO 15223-1:2021 ; EN ISO 20417:2021 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019- Not applicable ; EN ISO 10993-7:2008 ; EN 556-1:2001 AC:2006 ; EN ISO 11607-1:2020 ; EN ISO 11737-2:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ;
GMDN:	59049 - General-purpose medical fibre padding

Level	Type	Dimension	Stamp	Labels
 1	1 INNER flexible peel-open pack	134x140mm		
 2	1 DOUBLE Flexible peel-open pack	160x175mm		
 3	28 Folding box	374x308x245mm		labeled
 4	168 Carton box	786x389x643mm		labeled

Basic UDI	56056221113004J3
	EAN 1th level/nivel:05605622216706
	EAN 2th level/nivel:05605622416700
	EAN Carton Box/Caixa:05605622016702

Important Notes:	The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage. Easy to tear by the hand. Conformable around body contours.
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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
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Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended purpose	For orthopaedic cushioning.
	<i>Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility</i>

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	2860
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ISSUED BY: Quality Management Department, 2023/07/10

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