


Description: Muslin bandages

Final dimensions:	5 m x6 cm
Composition:	Cotton.
Size variation:	±10 %
Construction:	LIG PANO 1 FIO
Weight/sqm:	aprox 48,90g/m2
Weight/piece:	> 13,3364g
Latex:	Free
PVC:	Free
Re use:	No
Shelf life:	120 months
CFU/g	<10 ²
Fibre identification	conform
pH (acidity/alkalinity)	conform
Foreign fibres	conform
Fluorescence	conform
Ether soluble substances	<0,50 %
Surface active substances	<2 mm
Water soluble substances	<0,50 %
Loss on drying	<8 %
Sulphated ash	<0,4 %
Starch and dextrine	absent



Nr and Revision Date:	12 -- 2020/10/06
CE Class:	I
CE mark:	CE

Compliance with: MDR (EU) 2017/745

Applicable norms:	EN_ISO_13485.2016 ; EN_ISO_13485.2016_AC18 ; EN_ISO_11737_1_2018 ; ISO_10993-1.2018 ; ISO_14698_1_2003 ; ASTM_F1980_16 ; EN_ISO_14971.2012 ; EN_ISO_15223-1.2016 ; EN_1041.2008_A1.2013 ;
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Level	Type	Dimension	Stamp	Labels
1	1 Cellophane		stamped	
2	220 Carton box	285x253x311mm		labeled

Basic UDI	56056221024002J4
	EAN 1th level/nivel:05605622200477
	EAN Carton Box/Caixa:05605622000473

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.
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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
Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	Intended to immobilize limbs or support dressing material in the human body <i>Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility.</i>

Non-harmonized symbols used in article labeling


MD

threads/with selvages
Medical Device

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	155
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