Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 488-030

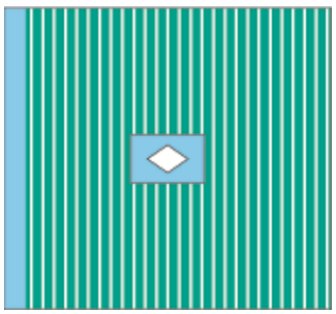
Alias: 488999030

Brand: COVREL SURGICAL DRAPES

DRQ 14/21 REV.02 2024/09/20

Description:	Epidural drape

STERILE EO | isento Latex free | isento PVC free



Final dimensions:	75 cm x75 cm x 2 ply
Composition:	PET/PE film,Polyethylene film,Viscose nonwoven.
Size variation:	±5 %
Construction:	Drapes LA
Cut:	10x12
Adhesive:	5x75
Adhesive:	17x15
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	green
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Class.EN 13795-1:2019	HIGH PERFORMANCE
Resist Micro.Penetra.Wet	6,0 IB
Linting	<4.0 log10lint count
Resist. liq. penetration	>100 cmH2O
Cleanliness- microbial	N.A. CFU/100cm^2
Sterility Assur. Level_SAL	≤10^-6
Flammability (16CFR1610)	**Class 3**
Flammability-Prim.ignition	I4_21 (ignition<4s)
Flammability-Prim.penetra	P4_21(<1s to 10mW)
Dry Bursting Strength	>120 kPa
Wet Bursting strength	>100 kPa
Dry Tensile strength MD	≥60 N/5cm
Dry Tensile strength TD	≥20 N/5 cm
Wet Tensile strength MD	≥45 N/5cm
Wet Tensile strength TD	≥20 N/5cm

Nr and Revision Date:	25 -- 2025/08/21
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	ISO 11810:2015 ; 16CFR Part 1610 ; ISO TR 24971:2020 ; ISO TR 20416:2020 ; EN 17141:2020 ; ISO 14698-2:2003 ; ISO 8601-1:2019 ; IEC TR 62366-2:2016 ; EN ISO 10993-18:20 AMD1:23 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; ASTM F1886/F1886M-16 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; ASTM F1980-21 ; ISTA Standard 3E ; EN 13795-1:2019 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; EN ISO 14644-1:2015 ; ISO 14698-1:2003 ; ISTA Standard 2A ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2020 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; ISO 14644-5:2004 ; ISO 2759:2014 ; ISO 3037:2022 ; 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 ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ;
GMDN:	47783 - Patient surgical drape, single-use

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1	1	Flexible peel-open pack	134x200mm		
2	35	Folding box	216x151x308mm		labeled

20 PAP 3	350	Carton box	786x231x641mm		labeled

Basic UDI	56056221119009KP
	EAN 1th level/nivel:05605622225395
	EAN 2th level/nivel:05605622425399
	EAN Carton Box/Caixa:05605622025391

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.

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 purpose	As covering drape to prevent transfer of infective agents in surgical context.
	Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsib

Non-harmonized symbols used in article labeling		Nr of plies

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	1084

ISSUED BY: Quality Management Department, 2026/03/19

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