Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 4881-503

Alias: 488199503

Brand: COVREL SURGICAL DRAPES

DRQ 14/21 REV.03 2026/06/18

Description:	Utility drape

STERILE EO | isento Latex free | isento PVC free

Final dimensions:	75 cm x90 cm
Composition:	Polyethylene film,SB Polypropylene nonwoven hidrophobic.
Size variation:	±5 %
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.
Sterility Assur. Level_SAL:	≤10^-6
Fluorescence:	Absent
Class.EN 13795-1:2019:	STANDARD PERFORMANCE
Resist. Micro Penetr. Wet:	>2,8 IB
Cleanliness- microbial:	N.A. CFU/100cm^2
Linting:	<4,0 log10lint count
Resist. Liq.Penetration:	>70 (standard>30) cmH2O
Dry Bursting Strength:	>80 (standard>40) kPa
Wet Bursting strength:	>90 (standard>40) kPa
Dry Tensile Strength:	MD>45/CD>20 N/5cm
Wet Tensile Strength:	MD>45/CD>20 N/5 cm
Flammability (16CFR1610):	Class 3
Flammability-Prim.ignition:	I4_21 (ignition <4s)
Flammability-Prim.penetration:	P4_21 (<1s to 10mW)



Nr and Revision Date:	29 -- 2025/08/21
CE Class:	IEE
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	16CFR Part 1610 ; ISO 11810:2015 ; 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 F1929-23 ; ASTM F88/F88M-23 ; EN ISO 11737-1:18 A1:21 ; UDI FAQs ; EN 13795-1:2019 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; ASTM F1980 16 ; EN ISO 14644-1:2015 ; ISO 14698-1:2003 ; ISTA Standard 2A ; EN ISO 14971:2012 ; EN ISO 15223-1:2016 ; EN 1041:2008 A1:2013 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2020 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO10993-1:09 AC:10 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2009 ; EN ISO 10993-18:2020 ; ISO 14644-5:2004 ; ASTM D4169-23e1 ; ICH Q1A (2003) ; ISO 2759:2014 ; ISO 3037:2022 ; ASTM D7386-16 ; EN ISO 15223-1:2021 ; EN ISO 20417:2026 ; 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
EMDN:	T0210 - NON-SURGICAL DRAPES

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1	1	Flexible peel-open pack	134x200mm		
2	45	Folding box	216x151x308mm		labeled

20 PAP 3	450	Carton box	786x231x641mm		labeled

Basic UDI	56056221119085L7
	EAN 1th level/nivel:05605622214177
	EAN 2th level/nivel:05605622414171
	EAN Carton Box/Caixa:05605622014173

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 responsibility.

Environment - Packaging waste	Weight(gr) of packing material used in 100 pcs	927	

ISSUED BY: Quality Management Department, 2026/09/02

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