Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref:	**488-003**

Alias: 488999003

Brand:	COVREL SURGICAL DRAPES

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

Description:	Instrument table cover

STERILE EO

isento Latex free

isento PVC free



Final dimensions:	150 cm x2 m
Composition:	Polyethylene film,Viscose nonwoven.
Size variation:	±5 %
Construction:	MEC E
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	>80 kPa
Dry Tensile strength MD	≥70 N/5cm
Dry Tensile strength TD	≥20 N/5 cm
Wet Tensile strength MD	≥50 N/5cm
Wet Tensile strength TD	≥20 N/5cm
Absorption Capacity	>300 %

Nr and Revision Date:	23 -- 2025/10/16
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	EN 13795-1:2019 ; ICH Q1A (2003) ; EN ISO 14971:2019 ; EN ISO 20417:2021 ; EN ISO 15223-1:2021 ; ASTM D4332 01 ; ASTM D4169-23e1 ; EN ISO 10993-1:2020 ; ISO TR 24971:2020 ; ISO TR 20416:2020 ; EN 17141:2020 ; ISO 14698-2:2003 ; ISO 8601-1:2019 ; IEC 62366-1:2015 A1:2020 ; 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 ; UDI FAQs ; 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 A11:2021 ; ISO 14644-5:2004 ; ISO 2759:2014 ; ISO 3037:2022 ; ASTM D7386-16 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019- Not applicable ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ;
GMDN:	12535 - Medical equipment drape, single use;

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1 PAP	1	Flexible peel-open pack	200x290mm		
2 PAP	12	Carton box	312x213x247mm		labeled
3 PAP	72	Carton box	786x231x641mm		labeled

Basic UDI	56056221122012J6
	EAN 1th level/nivel:05605622223834
	EAN 2th level/nivel:05605622423838
	EAN Carton Box/Caixa:05605622023830

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	To cover equipment 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

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	3661

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

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