Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 4216-002

Alias: 421699002

Brand:

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

Description:	Stockinette Natural

STERILE | isento Latex free | isento PVC free



Final dimensions:	7,5 cm x100 cm
Composition:	100% Cotton.
Construction:	4216 Algodão 7,5cm
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	natural
Sterilization method:	Moist heat
Shelf life:	60 months
CFU/g	N.A.
Fluorescence	conform
Sterility Assur. Level_SAL	≤10^-6
Size variation	±10 %
Weigth/sqm	≥400 g/m^2
Hydrophobic properties	>10 s

Nr and Revision Date:	19 -- 2025/06/13
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	**IEC 62366-1:2015 A1:2020 ; EN ISO 10993-18:20 AMD1:23 ; ISO 14698-2:2003 ; ISO 11138-3:2017 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; ISO 14644-5:2004 ; IEC TR 62366-2:2016 ; ASTM F1886/F1886M-16 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; ISO TR 24971:2020 ; ISO TR 20416:2020 ; EN 17141:2020 ; ISO 8601-1:2019 ; ASTM F1980-21 ; EN ISO 17665:2024 ; BP Ribb CO Stockinete Mono-(partial compliance: compliance with basis weight, elasticity, fluorescence and water and ether-soluble substances) ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2020 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; EN ISO 14971:2019 ; EN ISO 11607-1:2020 ; EN ISO 14971:2019 A11:2021 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ; ISO 14698-1:2003 ; EN ISO 14644-1:2015 ; ISTA Standard 2A ; ASTM D4169-23e1 ; ASTM D7386-16 ; ISO 2759:2014 ; ISO 3037:2022 ; EN ISO 15223-1:2021 ; EN ISO 20417:2021 ;**
GMDN:	35374 - Stockinette

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1	1	INNER flexible peel-open pack	134x140mm		
2	1	DOUBLE Flexible peel-open pack	160x175mm		
3	40	Folding box	374x308x245mm		labeled
4	240	Carton box	786x389x643mm		labeled

Basic UDI	56056221114003J8
	EAN 1th level/nivel:05605622202945
	EAN 2th level/nivel:05605622402949
	EAN Carton Box/Caixa:05605622002941

Important Notes:	Please note that this is a knitted article where size was taken under normal working tension. Subjected to contraction when in loose situation. 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 general-purpose protective skin covering, namely for use as an under cast or splinting materials. For retention of dressing material
	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	2325

ISSUED BY: Quality Management Department, 2026/03/25

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