Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 4571-512

Alias: 457199512

Brand:

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

Description:	Gloves- Viscose

STERILE EO

isento Latex free

isento PVC free



Composition:	Viscose.
Construction:	Viscose 4571 L
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Size:	L
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g:	N.A.
Air Permeability:	>100 l/min/100cm2
Tens.strength bef. aging:	>90 N
Fluorescence:	Absence
pH (acidity or alkalinity):	5.0-8.0

Nr and Revision Date:	19 -- 2026/09/02
CE Class:	IEE
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	ISO TR 24971:2020 ; ISO 2859 1:2026 ; EN 556-1:2024 ; EN ISO 11607-1:20 A1:23 ; EN ISO 11607-2:20 A1:2023 ; ISO 8601-1:2019 AMD1:2022 ; EN ISO 14644-5:2025 ; EN ISO 15223-1:21 AMD2025 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2020 ; ISO 10993-7:2008 Amd1 2019 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:20 AMD1:23 ; EN ISO 10993-7:2008 ; EN ISO 10993-18:2020 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO 14644-1:2015 ; ISTA Standard 2A ; EN 17141:2020 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; ASTM D7386-16 ; ASTM F1886/F1886M-16 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; ISO 2759:2014 ; ASTM F1980-21 ; ISO 3037:2022 ; EN ISO 11135:2014 ; ISO TR 20416:2020 ; EN ISO 11135:14 A1:2019-Not applicable ; ISO 8601-1:2019 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ; EN ISO 15223-1:2021 ; EN ISO 20417:2026 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ;
GMDN:	60419 - Skin treatment/dressing-supportive glove/mitten, single-use
EMDN:	T0199 - GLOVES - OTHER

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1	2	Flexible peel-open pack	134x240mm		
2	70	Folding box	216x151x308mm		labeled
3	700	Carton box	786x231x641mm		labeled

Basic UDI	560562210270O3JT
	EAN 1th level/nivel:05605622059877
	EAN 2th level/nivel:15605622059874
	EAN Carton Box/Caixa:25605622059871

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 a barrier to protect the skin and prevent moisture-related skin damage, allergies or hand eczema/dermatitis.

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	567	

ISSUED BY: Quality Management Department, 2026/09/11

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