Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref:	4372-013

Alias: 437299013

Brand:	ZILLION® MEDICAL DISPOSABLES

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

Description:	Eye shield

STERILE EO

isento Latex free

isento PVC free



Final dimensions:	7.8 cm x 6.40 cm
Composition:	Copolymer.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	Transparent
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_SAL	≤10^-6
Size variation	±2 mm
Note	Perforated
Note	Resistant
Size	Adult

Nr and Revision Date:	60 -- 2026/01/29
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	EN 17141:2020 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; EN ISO 10993-18:20 AMD1:23 ; ISO 8601-1:2019 ; ASTM F1886/F1886M-16 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; ISO TR 24971:2020 ; ISO TR 20416:2020 ; ISO 14698-2:2003 ; UDI FAQs ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN 556-1:2001 AC:2006 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019-Not applicable ; 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 ; ASTM F1980 16 ; ISTA Standard 2A ; ASTM D4169-23e1 ; ASTM D7386-16 ; ISO 2759:2014 ; ISO 3037:2022 ; EN ISO 15223-1:2021 ; EN ISO 20417:2021 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ; EN ISO 14644-1:2015 ; ISO 14644-5:2004 ;
GMDN:	**65733 - Postsurgical transparent eye shield, vented**

PACKING

Level	Units	Type	Dimension	Stamp	Labels
22 PAP 1	1	Rigid peel-open pack	97x195mm		
21 PAP 2	25	Folding box	105x212X200mm		labeled
20 PAP 3	100	Carton box	416x223x223mm		labeled

Basic UDI	56056221161002K8
	EAN 1th level/nivel:05605622050232
	EAN 2th level/nivel:15605622050239
	EAN Carton Box/Caixa:25605622050236

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	Dispose according to applicable legislation and/or infection prevention standards for healthcare waste, to minimize potential risk of contamination, infection or pollution.
Intended purpose	To cover and protect the eye.
	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		Eye shield - adult

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	1679

ISSUED BY: Quality Management Department, 2026/03/10

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