Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 489-534

Alias: 489999534

Brand: ZILLION MEDICAL DISPOSABLES

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

Description:	Surgical bowl

STERILE EO

isento Latex free

isento PVC free



Composition:	Colourant,PP pharmaceutical grade.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	Blue
Capacity:	250 ml
Diameter:	105 mm
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g:	N.A.
Sterility Assur. Level_SAL:	≤10^-6
Size variation:	±2 mm
Height:	54 mm
Graduation:	Scale in mL and FLOZ
Tested in accordance w/:	BS5452:1977(adapted)

Nr and Revision Date:	51 -- 2026/09/03
CE Class:	IIa
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	BS 5452:1997-Specification for hospital hollow-ware made of plastics material (Partial compliance:non-compliance of 3: Dimensions, 5: Design and 10: Effect of sterilization as these are single-use devices it was not considered 50 cycles of sterilization acc: Appendix A) and 12: Marking absence of information on b) number of this British Standard and c) information regarding type and size engraved on the under surface): ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2020 ; EN 556-1:2024 ; ISO 11737-3:2023 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019-(Not applicable) ; EN 1422:2014 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; EN ISO 10993-18:20 AMD1:23 ; EN ISO 10993-7:08:AC:2009 ; ISO 10993-7:2008 Amd1 2019 ; EN ISO 11607-1:2020 ; EN ISO 11607-1:20 A1:23 ; EN ISO 11607-2:2020 ; EN ISO 11607-2:20 A1:2023 ; CEN ISO TS 16775 2021 ; EN 17141:2020 ; EN ISO 14644-1:2015 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; EN ISO 14644-5:2025 ; ISO 2759:2014 ; ISO 3037:2022 ; ISTA Standard 2A ; ISTA Standard 3E ; ASTM F1980-21 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; ASTM F1886/F1886M-25 ; ISO 2859 1:2026 ; ISO 8601-1:2019 ; ISO 8601-1:2019 AMD1:2022 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; ISO TR 24971:2020 ; EN ISO 15223-1:2021 ; EN ISO 15223-1:21 AMD2025 ; EN ISO 20417:2026 ; ISO TR 20416:2020 ;
GMDN:	42891 - General-purpose bowl, single-use
EMDN:	V0402 - CLINICAL USE TRAYS AND BOWLS

PACKING With Instructions for use

Level	Units	Type	Dimension	Stamp	Labels
1 (22 PAP)	1	Flexible peel-open pack	134x140mm		
2 (4 LDPE)	110	Plastic bag	1000x800x000mm		labeled
3 (20 PAP)	110	Carton box	586x388x317mm		labeled

Basic UDI	56056221200002HC
	EAN 1th level/nivel:05605622241340
	EAN 2th level/nivel:05605622441344
	EAN Carton Box/Caixa:05605622041346

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 temporarily hold organs or tissues. To hold or for preparation of medical devices such as catheters with medicinal solutions. To hold medicinal solutions - such as saline, contrast media, heparin, anesthetics (e.g., ropivacaine), or analgesics (e.g., sufentanil) - for injection, preparation, mixing, or dilution. To hold aqueous, saline solutions for irrigation To hold aqueous, saline or antiseptics solutions for wound cleansing. To hold antiseptics for disinfection of skin or mucosa.

Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility.

Non-harmonized symbols used in article labeling

Environment - Packaging waste	Weight(gr) of packing material used in 100 pcs	1073	

ISSUED BY: Quality Management Department, 2026/09/15

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