Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref:	**489-512**

Alias: 489999512

Brand:	ZILLION® MEDICAL DISPOSABLES

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

Description:	Pitcher

Composition:	PP pharmaceutical grade.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	translucent
Capacity:	1000 mL
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_SAL	≤10^-6
Height	115 mm
Graduation:	Scale in mL and FLOZ

STERILE EO

isento Latex free

isento PVC free



Nr and Revision Date:	41 -- 2024/02/29
CE Class:	IIa
CE mark:	CE1639
Compliance with:	MDR (EU) 2017/745
Applicable standards:	EN ISO 15223-1:2021 ; EN ISO 20417:2021 ; EN ISO 14971:2019 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; ISTA Standard 2A ; EN ISO 11135:14 A1:2019-(Not applicable) ; EN ISO 13485:2016 A11:2021 ; EN ISO 14971:2019 A11:2021 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; ISO 2759:2014 ; ISO 3037:2013 ; 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): ; CEN ISO TS 16775 2021 ; EN ISO 11135:2014 ; 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 ; ISO 10993-18:2020 AMD1:2022 ; ISO 11737-3:2023 ; ISO 14644-2:2015 ; ISO 14644-3:2019 ; ASTM F1886/F1886M-16 ; ASTM F1929-15 ; ASTM F88/F88M-21 ; EN 1422:2014 ; ASTM F1980-21 ; EN ISO 10993-7:08:AC:2009 ; ISO 10993-7:2008 Amd1 2019 ; ISTA Standard 3E ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; ISO 14644-1:2015 ; ISO 14644-5:2004 ; ISO 14698-1:2003 ;
GMDN:	42891 - General-purpose bowl, single-use

PACKING With Instructions for use

Level	Units	Type	Dimension	Stamp	Labels
22 PAP **1**	1	Flexible peel-open pack	200x290mm		
4 LDPE **2**	24	Plastic bag	1000x800x000mm		labeled
20 PAP **3**	24	Carton box	586x388x317mm		labeled

Basic UDI	56056221200002HC
	EAN 1th level/nivel:05605622232461
	EAN 2th level/nivel:05605622432465
	EAN Carton Box/Caixa:05605622032467

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 local laws rules, regulations 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 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 responsib

Non-harmonized symbols used in article labeling

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	4017

ISSUED BY: Quality Management Department, 2025/04/01

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