Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref:	**489-530**

Alias: 489999530

Brand: ZILLION® MEDICAL DISPOSABLES

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

Description:	Guidewire bowl

Final dimensions:	24 cm x24 cm
Composition:	Colourant,PP pharmaceutical grade.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	blue
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_SAL	≤10^-6
Height	7,0 cm
Graduation:	Scale in mL and FLOZ

STERILE EO

isento Latex free

isento PVC free



Nr and Revision Date:	39 -- 2024/03/21
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	MDR (EU) 2017/745
Applicable standards:	EN ISO 10993-18:2020 ; EN ISO 10993-1:2020 ; EN ISO 14971:2019 ; EN ISO 15223-1:2021 ; EN ISO 20417:2021 ; ASTM D4169-22 ; ISO 3037:2013 ; ISO 2759:2014 ; EN ISO 13485:2016 A11:2021 ; EN ISO 14971:2019 A11:2021 ; ASTM D7386-16 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019-Not applicable ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ; EN ISO 10993-7:2008 ; EN ISO 11737-2:2020 ; 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 14644-2:2015 ; ISO 14644-3:2019 ; ASTM F1886/F1886M-16 ; ASTM F1929-15 ; ASTM F88/F88M-21 ; ISO 11737-3:2023 ; EN 1422:2014 ; BS 5452:1997-(Partial compliance: Non-compliance of 3: Dimensions and 5: Design as they have been adapted according with state-of-art devices; 10: Effect of sterilization (Method of sterilization considering 50 cycles according with Appendix A) as these are single-use devices; 12: Marking as they do not present 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 556-1:2001 AC:2006 ; ISO 14644-1:2015 ; ISO 14644-5:2004 ; ISO 14698-1:2003 ; ISTA Standard 2A ;
GMDN:	66092 - Guidewire bowl

Important Notes:	**Plastic sleeve inside carton boxes**

PACKING

Level	Units	Type	Dimension	Stamp	Labels
22 PAP **1**	1	Flexible peel-open pack	400x290mm		
4 LDPE **2**	36	Plastic bag	1200x1100x000mm		labeled
20 PAP **3**	36	Carton box	786x389x643mm		labeled

Basic UDI	56056221160002JZ
	EAN 1th level/nivel:05605622239880
	EAN 2th level/nivel:05605622439884
	EAN Carton Box/Caixa:05605622039886

Important Notes:	Guidance scale present in the guidewire bowl is a guidance scale, it is not validated-
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	For preparation and temporary storage of guidewire while keeping it in place and hydrated.
	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		
	≈	Guidance scale, not validated
		Prior to use please flush the container with sterile solution.

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	6867

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

CONFIDENTIAL: The information contained herein is confidential and belongs to Bastos Viegas, s.a. It is provided for specific purposes and in connection with established agreements. It is not permitted disclosure, reproduction, copying or distribution, in whole or in part, for other purposes or to any third parties.