Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref:	**489-054**
Alias:	489999054

Brand:	ZILLION® MEDICAL DISPOSABLES

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

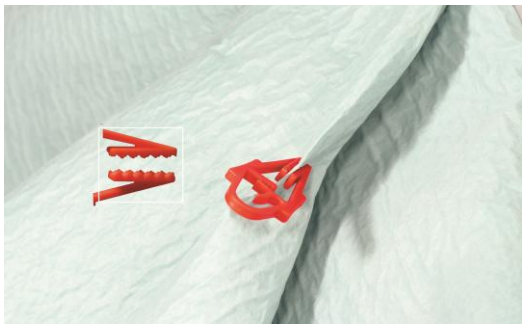
Description:	Towel clamp

Composition:	Colourant,Polyacetal.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_SAL	≤10^-6

STERILE EO

isento Latex free

isento PVC free



Nr and Revision Date:	20 -- 2024/01/31
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	MDR (EU) 2017/745
Applicable standards:	ASTM D4169-22 ; EN ISO 14971:2019 ; EN ISO 20417:2021 ; EN ISO 10993-18:2020 ; EN ISO 10993-1:2020 ; EN ISO 15223-1:2021 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; EN ISO 14971:2019 A11:2021 ; ISO 2759:2014 ; ISO 3037:2013 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019- Not applicable ; EN ISO 13485:2016 A11:2021 ; CEN ISO TS 16775 2021 ; EN ISO 11737-2:2020 ; EN ISO 10993-7:2008 ; ASTM D7386-16 ; ASTM F1980-21 ; 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 ; UDI FAQs ; 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 ; EN ISO 15223-1:2016 ;
GMDN:	65743 - Towel clamp, single-use

PACKING

Level	Units	Type	Dimension	Stamp	Labels
22 PAP **1**	1	Flexible peel-open pack	100x125mm		
20 PAP **2**	60	Folding box	256x122x151mm		labeled
20 PAP **3**	1080	Carton box	786x386x321mm		labeled

Basic UDI	56056221153004KF
	EAN 1th level/nivel:05605622232843
	EAN 2th level/nivel:05605622432847
	EAN Carton Box/Caixa:05605622032849

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 holding and positioning surgical drapes and/or towels during medical procedures.
	Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsib

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	377

ISSUED BY: Quality Management Department, 2025/08/07

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