Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 489-007

Alias: 489999007

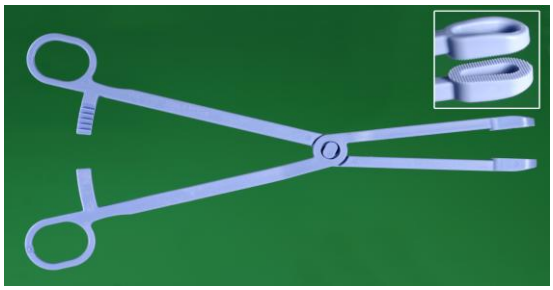
Brand: ZILLION® MEDICAL DISPOSABLES

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

Description:	Sponge forceps

STERILE EO | isento Latex free | isento PVC free

Final dimensions:	24 cm
Composition:	Colourant,Reinforced Polypropylene.
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



Nr and Revision Date:	38 -- 2024/01/31
CE Class:	IIa
CE mark:	CE1639
Compliance with:	MDR (EU) 2017/745
Applicable standards:	EN ISO 11135:2014 ; EN ISO 10993-18:2020 ; EN ISO 10993-1:2020 ; EN ISO 15223-1:2021 ; EN ISO 20417:2021 ; EN ISO 14971:2019 ; ISTA Standard 2A ; ASTM D4169-22 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; EN ISO 14971:2019 A11:2021 ; ISO 2759:2014 ; ISO 3037:2013 ; EN ISO 11135:14 A1:2019-Not applicable ; CEN ISO TS 16775 2021 ; ISO TR 24971:2020 ; 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 ; EN ISO 13485:2016 A11:2021 ; EN ISO 10993-7:2008 ; ISO 10993-7:2008 Amd1 2019 ; ISO 11737-3:2023 ; ISO 10993-18:2020 AMD1:2022 ; EN ISO 11737-2:2020 ; EN 17141:2020 ; ISO 14698-2:2003 ; ISO 14644-2:2015 ; ISO 14644-3:2019 ; ASTM D7386-16 ; ASTM F1886/F1886M-16 ; ASTM F1929-15 ; ASTM F88/F88M-21 ; ASTM F1980-21 ; ISO TR 20416:2020 ; ISO 2859 1:1999 ; ISO 8601-1:2019 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ;
GMDN:	62490 - Dressing/utility forceps, scissors-like, single use

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1	1	Flexible peel-open pack	134x310mm		
2	35	Folding box	216x151x308mm		labeled
3	350	Carton box	786x231x641mm		labeled

Basic UDI	56056221207002JV
	EAN 1th level/nivel:05605622232966
	EAN 2th level/nivel:05605622432960
	EAN Carton Box/Caixa:05605622032962

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 swabs for absorption during surgery or woundcare procedures or for skin disinfection 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	1263

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