Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 4891-526

Alias: 489199526

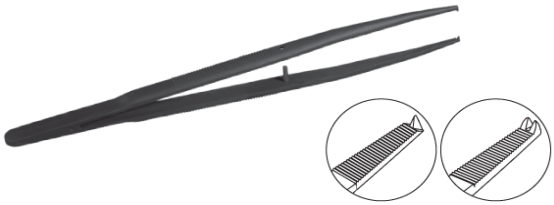
Brand: ZILLION® BLACK

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

Description:	Tissue forceps

STERILE EO | isento Latex free | isento PVC free

Final dimensions:	20 cm
Composition:	High performance polymer.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	Grey
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g:	N.A.
Sterility Assur. Level_SAL:	≤10^-6
Size variation:	±2 mm



Nr and Revision Date:	30 -- 2025/10/29
CE Class:	IIa
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	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 ; 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:	62479 - Surgical soft-tissue manipulation forceps, tweezers-like, single-use
EMDN:	V9012 - NON-SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE-USE

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1	1	Rigid peel-open pack	53x228mm		
2	19	Folding box	231x056x212mm		labeled
3	76	Carton box	245x243x223mm		labeled

Basic UDI	56056221204002J8
	EAN 1th level/nivel:05605622049908
	EAN 2th level/nivel:15605622049905
	EAN Carton Box/Caixa:25605622049902

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:	For grasping and to hold and stabilize tissues. For holding other devices.

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

Environment - Packaging waste	Weight(gr) of packing material used in 100 pcs	1495	

ISSUED BY: Quality Management Department, 2026/08/24

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