Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 4891-532

Alias: 489199532

Brand: ZILLICA BLAC

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

Description:	Roux Retractor

STERILE EO | isento Latex free | isento PVC free

Final dimensions:	17 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
Length:	168,5±0,5 mm
Width front:	19,2±0,5 mm
Width back:	13,4±0,5 mm



Nr and Revision Date:	26 -- 2026/04/15
CE Class:	IIa
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	ISO 2859 1:2026 ; EN ISO 10993-18:2020 ; EN ISO 10993-1:2020 ; EN ISO 14971:2019 ; EN ISO 15223-1:2021 ; EN ISO 20417:2026 ; ISTA Standard 2A ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; EN ISO 14971:2019 A11:2021 ; ISO 2759:2014 ; ISO 3037:2022 ; EN ISO 11135:14 A1:2019-Not applicable ; CEN ISO TS 16775 2021 ; EN ISO 10993-7:2026 ; EN ISO 10993-2:2022 ; EN ISO 10993-12:2021 ; EN ISO 10993-12:2021 AMD1:2025 ; ISO TR 24971:2020 ; EN 17141:2020 ; ISO 8601-1:2019 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; EN ISO 10993-18:20 AMD1:23 ; ISO 11737-3:2023 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; EN 556-1:2024 ; EN 1422:2014 ; EN ISO 14644-5:2025 ; ASTM F1886/F1886M-25 ; EN ISO 10993-4:2017 ; EN ISO 10993-4:2017 AMD1:2025 ; EN ISO 10993-5:2009 A11:2025 ; EN ISO 10993-5:2009 ; EN ISO 10993-10:2023 ; EN ISO 10993-23:2021 ; EN ISO 10993-23:2021 AMD1:2025 ; EN ISO 14644-1:2015 ; EN ISO 10993-11 2018 ; ASTM F1980-21 ; EN ISO 11607-2:20 A1:2023 ; EN ISO 11607-1:20 A1:23 ; ISO 8601-1:2019 AMD1:2022 ; EN ISO 15223-1:21 AMD2025 ; ISO TR 20416:2020 ; EN ISO 11737-2:2020 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; ISO 11135:2014 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11135:2014 ;
GMDN:	62562 - Hand-held surgical retractor, single-use
EMDN:	V9099 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER

PACKING With Instructions for use

Level	Units	Type	Dimension	Stamp	Labels
1 (4 LDPE)	1	Rigid peel-open pack	97x195mm		
2 (20 PAP)	7	Carton box	200x105x212mm		labeled
3 (20 PAP)	28	Carton box	416x223x223mm		labeled

Basic UDI	56056221209002KB
	EAN 1th level/nivel:05605622051680
	EAN 2th level/nivel:15605622051687
	EAN Carton Box/Caixa:25605622051684

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:	To hold back soft tissues and organs in order to expose the surgical field

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

Non-harmonized symbols used in article labeling

Environment - Packaging waste	Weight(gr) of packing material used in 100 pcs	3844	

ISSUED BY: Quality Management Department, 2026/07/27

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