

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

Description:	Roux Retractor
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

STERILE EO



isento
Latex
free

isento
PVC
free



Nr and Revision Date:	19 -- 2024/01/31
CE Class:	Ila
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 ; ISTA Standard 2A ; ICH Q1A (2003) ; ASTM D4169-22 ; ASTM D4332 01 ; 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 ; 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 11737-3:2023 ; 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 11135:2014 ; ISO 14644-1:2015 ; ISO 14644-5:2004 ; ISO 14698-1:2003 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11135:2014 ;
GMDN:	62562 - Hand-held surgical retractor, single-use

PACKING					
Level	Units	Type	Dimension	Stamp	Labels
 4	1	1 Rigid peel-open pack	97x195mm		
 20	2	7 Carton box	200x105x212mm		labeled
 20	3	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.
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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	To hold back 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

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