

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

Description:	Iris forceps
Final dimensions:	10.5 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
Note	Non-toothed

STERILE EO



isento
Latex
free

isento
PVC
free



Nr and Revision Date:	30 -- 2024/09/23
CE Class:	Ila
CE mark:	CE1639

Compliance with:	MDR (EU) 2017/745
Applicable standards:	ISTA Standard 2A ; ASTM D4169-22 ; EN ISO 14971:2019 ; EN ISO 11607-1:2020 ; EN ISO 20417:2021 ; EN ISO 11607-2:2020 ; EN ISO 10993-18:2020 ; EN ISO 10993-1:2020 ; EN ISO 15223-1:2021 ; 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 11135:2014 ; 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 ISO 11135:2014 ; 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:	62479 - Surgical soft-tissue manipulation forceps, tweezers-like, single-use

PACKING					
Level	Units	Type	Dimension	Stamp	Labels
4	1	1 Rigid peel-open pack	53x148mm		
20	21	Folding box	151x056x212mm		labeled
20	84	Carton box	245x163x223mm		labeled

Basic UDI	56056221204002J8
	EAN 1th level/nivel:05605622248080
	EAN 2th level/nivel:05605622448084
	EAN Carton Box/Caixa:05605622048086

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	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	977
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ISSUED BY: Quality Management Department, 2024/11/21

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