

## Product Specification

Ref: **4891-508**

Alias: 489199508

Brand:

**ZILLION<sup>®</sup>**  
**BLACK**

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

<b>Description:</b>	Tissue forceps
<b>Final dimensions:</b>	14.5 cm
<b>Composition:</b>	High performance polymer.
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>CMR:</b>	Free
<b>Endocrine Disruptors:</b>	Free
<b>Colour:</b>	Grey
<b>Sterilization method:</b>	Ethylene Oxide
<b>Shelf life:</b>	60 months
<b>CFU/g</b>	N.A.
<b>Sterility Assur. Level_SAL</b>	≤10 <sup>-6</sup>

STERILE EO






isento  
Latex  
free

isento  
PVC  
free



<b>Nr and Revision Date:</b>	28 -- 2024/01/31
<b>CE Class:</b>	Ila
<b>CE mark:</b>	CE1639
<b>Compliance with:</b>	MDR (EU) 2017/745

<b>Applicable standards:</b>	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 ;
<b>GMDN:</b>	62479 - Surgical soft-tissue manipulation forceps, tweezers-like, single-use

PACKING					
Level	Units	Type	Dimension	Stamp	Labels
	1	1 Rigid peel-open pack	53x173mm		
	2	19 Folding box	176x056x212mm		labeled
	3	76 Carton box	245x188x223mm		labeled

<b>Basic UDI</b>	56056221204002J8
	EAN 1th level/nivel:05605622247984
	EAN 2th level/nivel:05605622447988
	EAN Carton Box/Caixa:05605622047980

<b>Important Notes:</b>	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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<b>Storage instructions</b>	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.
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<b>Waste instructions</b>	Dispose according to local laws rules, regulations and/or infection prevention standards for healthcare waste, to minimize potential risk of contamination, infection or pollution.
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<b>Intended purpose</b>	For grasping and to hold and stabilize tissues. For holding other devices.
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*Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility*

<b>Environment - Packaging waste</b>	Weight (gr) of packing material used in 100 pcs	1192
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**ISSUED BY: Quality Management Department, 2024/11/21**

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