

Product Specification

Ref: 4891-516

Alias: 489199516

Brand:

ZILLION[®]
BLACK

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

Description: Spencer-Wells Forceps

Final dimensions:	18.5 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

STERILE EO



isento
Latex
free

isento
PVC
free



Nr and Revision Date:	32 -- 2024/01/31
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 TS 16775:2014 ; 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:	61478 - Surgical soft-tissue manipulation forceps, scissors-like, single-use

PACKING					
Level	Units	Type	Dimension	Stamp	Labels
	1	1 Rigid peel-open pack	130x235mm		
	2	33 Folding box	238x133x212mm		labeled
	3	132 Carton box	553x250x223mm		labeled

Basic UDI	56056221203002HZ
	EAN 1th level/nivel:05605622248066
	EAN 2th level/nivel:05605622448060
	EAN Carton Box/Caixa:05605622048062

Important Notes:	-These forceps are not intended for clamping or grasping the umbilical cord during a C-section.
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 local laws rules, regulations and/or infection prevention standards for healthcare waste, to minimize potential risk of contamination, infection or pollution.
Intended purpose	For hemostasis/clamp vessels and/or grasping tissues.

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	2584
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ISSUED BY: Quality Management Department, 2024/11/21

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