

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

Description: Skin staple remover

Final dimensions:	12.5 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:	35 -- 2024/01/31
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

ISO TR 24971:2020 ; ISO TR 20416:2020 ; 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 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 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2009 ; EN ISO 11737-2:2020 ; EN ISO 14971:2012 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO10993-1:09 AC:10 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2009 ; EN ISO 10993-18:2020 ; ASTM F1980 16 ; ISO 14698-1:2003 ; ISO 14644-1:2015 ; ASTM D4169-22 ; ISO 14644-5:2004 ; ISTA Standard 2A ; ASTM D4332 01 ; ICH Q1A (2003) ; ASTM D7386-16 ; EN ISO 15223-1:2016 ; ISO 2759:2014 ; EN 1041:2008 A1:2013 ; ISO 3037:2013 ; EN ISO 15223-1:2021 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019-Not applicable ; EN ISO 20417:2021 ; EN ISO 10993-7:2008 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ;

Applicable standards:

GMDN: 47192 - Surgical staple remover, single-use

PACKING With Instructions for use

Level	Units	Type	Dimension	Stamp	Labels
 4	1	1 Rigid peel-open pack	97x195mm		
 20	2	28 Carton box	200x105x212mm		labeled
 20	3	112 Carton box	416x223x223mm		labeled

Basic UDI	56056221158002LE
	EAN 1th level/nivel:05605622248110
	EAN 2th level/nivel:05605622448114
	EAN Carton Box/Caixa:05605622048116

Important Notes: Instructions for use are supplied with the device in order for it to be used correctly and as intended, as the skin staple remover should be placed according with the instructions for use, in order to avoid the risk of pain or skin damage.-

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 removal of surgical skin staples.
	<i>Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility</i>

Non-harmonized symbols used in article labeling
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Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	1885
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ISSUED BY: Quality Management Department, 2024/11/21

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