






Description: Catheterization set

Composition:	Please see below.	STERILE	EO
Latex:	Free		
PVC:	Free		
Re use:	No		
CMR:	Free		
Endocrine Disruptors:	Free		
Sterilization method:	Ethylene Oxide		
Shelf life:	60 months		
CFU/g	N.A.		
Sterility Assur. Level_SAL	≤10 ⁻⁶		






Nr and Revision Date:	73 -- 2023/08/28
CE Class:	Ila
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	EN ISO 11737-2:2020 ; ISO 8601-1:2019 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; EN 17141:2020 ; ASTM F1980-21 ; ISO 14644-2:2015 ; ISO 14644-3:2019 ; ASTM F1886/F1886M-16 ; ASTM F1929-15 ; ASTM F88/F88M-21 ; ISO 14698-2:2003 ; ISO 2859 1:1999 ; ISO TR 24971:2020 ; ISO TR 20416:2020 ; ISO 10993-18:2020 AMD1:2022 ; ISO 11737-3:2023 ; UDI FAQs ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO 10993-1:2020 ; ISTA Standard 2A ; ASTM D4169-22 ; ICH Q1A (2003) ; ASTM D7386-16 ; ISO 2759:2014 ; ISO 3037:2013 ; EN ISO 15223-1:2021 ; EN ISO 20417:2021 ; EN 556-1:2001 AC:2006 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019 ; EN ISO 10993-7:2008 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ; ISO 14644-5:2004 ; ISO 14644-1:2015 ; ISO 14698-1:2003 ;
GMDN:	61355 - Urethral catheterization support kit, urinary drainage

Level	Type	Dimension	Stamp	Labels
 1	1 Flexible peel-open pack	134x240mm		
 2	20 Folding box	215x313x248mm		labeled
 3	120 Carton box	786x231x641mm	stamped	labeled




Basic UDI	56056221255037LR
	EAN 1th level/nivel:05605622244099
	EAN 2th level/nivel:05605622444093
	EAN Carton Box/Caixa:05605622044095

COMPONENTS	QUANTITY	COMPOSITION
 489999320 Tray, 18x9,5x2,5cm, translucent	1	PP pharmaceutical grade.
489999365 Forcep 13cm, green	1	Colourant, Reinforced Polypropylene.
  744002003 Nonwoven swab 10x10cm, 4 plies, 30 g/sq.m	2	Viscose/Polyester Nonwoven.
744001003 Nonwoven ball 17x20cm, 30 g/sq.m "F"	2	Silicone ring, Viscose/Polyester Nonwoven.
744001001 Nonwoven ball 10x10cm, 30 g/sq.m "D"	5	Silicone ring, Viscose/Polyester Nonwoven.
745000504 Protection field - wrapping field 50x50cm	1	Cellulose, Polyethylene film.

741001200	Protection field (folded) 50x80cm w/cut 30cm	1	Cellulose, Polyethylene film.
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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	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended purpose	Intend to contain all the single use device components required for vesical catheterization procedures
<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		Do not cut
		Do not unfold
		F/invasive procedures, prior to use please flush the container w/sterile solution

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	2148
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ISSUED BY: Quality Management Department, 2023/12/21

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