

158040 Gauze

Swabs and sponges for a wide variety of wounds

Product details

Product group name : Gauze swab

Size : 10cm x 10cm

Descriptive feature : Swabs

Sterile : Sterile

Brand : Gauze Swab

Equivalences : 153600

Images



Delivered items

158040-15

Sales released in: Algeria, Belgium, Bulgaria, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Kuwait, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Qatar, Romania, Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey

Country of origin: China

Shelf life: 3 years

Sterilization method: EtO

Production Responsibility: Winner Medical (Chongyang) Co., Ltd. No. 8, Jincheng Avenue, Tiancheng Town, 437500. Chongyang, Hubei Province, China

Find out more at www.molnlycke.com

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Packing information: First packaging layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a corrugated board dispenser box. Third layer is a corrugated board transport box.

Is suitable for Tray: No

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7332430072849			39.3 cm3	4.5 g / -
Consumer pack	2	7332430407184	7332430407184			
Dispenser box	150	7332430404459	7332430404459			
Transport box	1500	7332430402233	7332430402233	284x786x264 mm	58.9 dm3	6.7 / 3.2 kg
Pallet	36000	7332430402226		800x1200x1782 mm		

Material

Animal tissues :	No
Human blood derivatives :	No
Natural rubber latex :	No
Medicinal substances :	No
Phthalates :	No
Polyvinyl chloride :	No

Product Composition Fibre, Gauze and Nonwoven Products

Product Component	Composition
Absorption material	Cotton

Product Performance Conventional Wound Dressing Products

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Acidity/Alkalinity	EN 14079 part 5.3	T-314	N/A	No pink colour	Approved
Fluorescence	EN 14079 part 5.5	T-318	N/A	Visual according to EN 14079	Approved

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Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Thread count Weft	EN 14079 part 5.6	T-358	Threads/100 mm	70±4	69
Thread count Warp	EN 14079 part 5.6	T-358	Threads/100 mm	100±5	100
Grammage of one ply material	EN 14079 part 5.7	T-266	g/m²	≥ 23	23
Breaking load Warp	EN 14079 part 5.8	T-1166	N/50 mm	≥ 50	69
Breaking load Weft	EN 14079 part 5.8	T-1166	N/50 mm	≥ 30	62
Sinking time	EN 14079 part 5.9	T-217	s	≤ 10	1
Ethyl acetate soluble substances	EN 14079 part 5.10	N/A	%	≤ 0,50	0,17
Surface active substances	EN 14079 part 5.11	T-315	mm	≤ 2	0
Water soluble substance	EN 14079 part 5.12	T-316	%	≤ 0,50	0
Starch and Dextrin	EN 14079 part 5.13	T-316	N/A	Visual according to EN 14079	Approved
Extractable colouring matter	EN 14079 part 5.14	T-324	N/A	Visual according to EN 14079	Approved
Loss on drying %	EN 14079 part 5.15	N/A	%	≤ 8	5,2
Sulphated ash	EN 14079 part 5.16	T-322	w%	≤ 0,40	0,15
Liquid absorptive capacity	ISO 9073-6 part 5	T-215	%	Not specified	600
Linting, dry	ISO 9073-10 /SS-EN 13795	T-1006	Number of particles	Not specified	2500

Technical

Dimension

Dimension text	Dimension value
Product	10 cm x 10 cm

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Classifications

Regulation type(s)	MDR Class IS	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :	MDR 722028			
Intended Purpose :	Gauze is intended for wound cleansing, skin cleansing e.g. before a surgical operation, and absorption of exudates when used as a secondary dressing.	Gauze is intended for wound cleansing, skin cleansing e.g. before a surgical operation, and absorption of exudates when used as a secondary dressing.	Gauze is intended for wound cleansing, skin cleansing e.g. before a surgical operation, and absorption of exudates when used as a secondary dressing.	Gauze is intended for wound cleansing, skin cleansing e.g. before a surgical operation, and absorption of exudates when used as a secondary dressing.
MDR Classification Rule :	4			
Conformity Annexes :	IX			
Measuring Function :	No			
Notified body medical devices/PPE :	BSi 2797	Local Authority MEA	Local Authority MEA	Local Authority MEA
510(k) clearance number :		NA		NA
Regulatory Released :	Belgium, Bulgaria, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland	Algeria	Turkey	Qatar

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Classifications

Regulation type(s)	Locally Regulated
CE Certificate Number :	
Intended Purpose :	Gauze is intended for wound cleansing, skin cleansing e.g. before a surgical operation, and absorption of exudates when used as a secondary dressing.
MDR Classification Rule :	
Conformity Annexes :	
Measuring Function :	
Notified body medical devices/PPE : Local Authority Kuwait	
510(k) clearance number :	
Regulatory Released :	Kuwait

Applied standards : The standards presented below is a selection of the most essential standards that are adhered to.

EN 1041, EN 556-1, EN 14079, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-7, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, EN ISO 10993-10, ISO 14001

Removable label

No

GMDN Code (Global Medical Device Nomenclature)

48134 Woven gauze pad, sterile

UNSPSC

42311512 Gauze Sponge

Commodity Code

3005903100 Gauze and articles of gauze

CE Responsibility / Legal Manufacturer

Mölnlycke Health Care AB, Gamlestadsvägen 3c, Box 13080, SE-402 52 Goteborg Sweden

Basic UDIDI

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