

Description:

Gauze swabs

Brand:






Final dimensions:	7,5 cm x 7,50 cm x 8 ply
Composition:	Cotton.
Size variation:	±10 %
Construction:	Gauze 13threads/sqcm
Weight/sqm:	> 17,00g/m ²
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Counting Efficiency approx	95 % (see note below)
Sterilization method:	Moist heat
Shelf life:	60 months
Liq Retention Cap/pc	> 5,007g water
CFU/g	N.A.
Sterility Assur. Level_SAL	≤10 ⁻⁶
Fibre identification	conform
pH (acidity/alkalinity)	conform
Foreign fibres	conform
Fluorescence	conform
Ether soluble substances	<0,50 %
Surface active substances	<2 mm
Water soluble substances	<0,50 %
Starch and dextrine	conform
Extract colouring matter	conform
Loss on drying	<8 %
Liquid absorptive capacity	>600 %
Sulphated ash	<0,40 %
Sinking time	<10 s
Thread count warp	70±4 Threads/100mm
Thread count weft	60±4 Threads/100mm
Min. breaking load warp	>35 N/5 cm
Min. breaking load weft	>20 N/5 cm

Nr and Revision Date:	19 -- 2022/10/10
CE Class:	Ila
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

EN ISO10993-1:09 AC:10 ; EN ISO 10993-18:2009 ; ASTM D4169-22 ; EN ISO 14971:2019 ; EN ISO 11607-1:2020 ; ASTM D4332 01 ; ICH Q1A (2003) ; 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 13485:2016 A11:2021 ; CEN ISO TS 16775 2021 ; EN 14079:2003 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; EN ISO 11737-2:2009 ; EN ISO 17665-1:2006 ; ISO 10993-1:2018 ; EN ISO 10993-5:2009 ; EN ISO 10993-10:2013 ; ISTA Standard 2A ; ASTM F1980 16 ; ISO 14698-1:2003 ; ISO 14644-1:2015 ; ISO 14644-5:2004 ; EN ISO 14971:2012 ; EN ISO 15223-1:2016 ; EN 1041:2008 A1:2013 ;





Applicable norms:

GMDN: 48134 - Woven gauze pad

Level	Type	Dimension	Stamp	Labels
 1	5 Flexible peel-open pack	100x125mm		
 2	200 Folding box	104x128x360mm		labeled
 3	3600 Carton box	786x386x321mm		labeled
Basic UDI	56056221252002KH			
	EAN 1th level/nivel:05605622210377			
	EAN 2th level/nivel:05605622410371			
	EAN Carton Box/Caixa:05605622010373			

Important Notes:	The swabs shall only be used as presented in its original size. They must not be opened, unfolded or altered in size, cut or modified in any way during use, as this will be against the manufacturer intended use for the swab.-
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.

CountingEfficiency approx	Surgeons and nurses shall never assume that number of surgical sponges, in each pack, is exact at all times.
	The usual counting efficiency of Bastos Viegas for this article is indicated above in "Counting Efficiency".The tracking of sponges is full responsibility of the healthcare professionals.
	In order to avoid retained surgical sponges following surgical operation, (1) follow rigorous manual counting protocols,
	(2) use sponges marked with a radiopaque marker, as well as, (3) careful examination of the abdomen by the operating surgeon before closure.
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	For general wound dressing procedures, including wound cleansing, absorption of blood and exudates, wound coverage and protection.-
	For skin disinfection procedures with antiseptics.-
	For swabbing and absorbing blood and fluids during surgery. To support organs or tissues during surgical procedures.-
	<i>Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsib</i>

Non-harmonized symbols used in article labeling		plies
		threads
		Do not cut
		Do not unfold

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	101
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ISSUED BY: Quality Management Department, 2023/04/03

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