



Description: Gauze ball w/elastic ring

Final dimensions:	20 cm x20 cm
Composition:	Cotton,Silicone ring.
Size variation:	±10 %
Diameter:	50mm
Construction:	Gauze 20threads/sqcm
Weight/sqm:	> 27,00g/m ²
Weight/piece:	> 0,9818g
Latex:	Free
PVC:	Free
Re use:	No
CountingEfficiency approx	95 % (see note below)
Round diameter:	40 mm
Sterilized by:	Moist heat
Shelf life:	60 months
Liq Retention Cap/pc	> 4,909g water
CFU/g	N.A.
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	>400 %
Sinking time	<10 s
Thread count warp	120±6 Threads/100mm
Thread count weft	80±5 Threads/100mm
Min. breaking load warp	>60 N/5cm
Min. breaking load weft	>35 N/5cm
Size	F



Nr and Revision Date:	5 -- 1998/12/21
CE Class:	Ila
CE mark:	CE0120
Directive:	MDD 93/42/ EEC amended by 2007/47/EC

Applicable norms:	EN ISO 13485:2016 ; EN 1041+A1:2013 ; EN ISO 11607-1:2009 ; EN ISO 11607-2:2006 ; EN ISO 11737-1:2006 ; EN ISO 11737-2:2009 ; EN 556-1:2001 ; EN 14079:2003 ; EN ISO 17665-1 :2006 ; ISO/TS 17665-2:2009 ; EN 285:2006+A2:2009 ; EN ISO 14971:2012 ; EN ISO 10993-1/AC:2010 ; EN 1041:2008 ; EN ISO 11737-1:2006/AC:2009 ; EN 556-1:2001/AC:2006 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ;
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Level	Type	Dimension	Stamp	Labels
1	5 Flexible peel-open pack	100x125mm	stamped	
2	150 Folding box	104x128x360mm - Imp. 2		labeled
3	2700 Carton box	780x380x315mm		labeled

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 use	For wound cleansing, skin disinfection and absorbing blood during surgery.

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	123
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ISSUED BY: Quality Management Department, 2019/08/08

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