



Description:	Gauze swab
Final dimensions:	5 cm x5 cm x 16 ply
Composition:	Cotton.
Size variation:	±10 %
Construction:	Gauze 17threads/sqcm
Weight/sqm:	> 23,00g/m2
Latex:	Free
PVC:	Free
Re use:	No
CountingEfficiency approx	95 % (see note below)
Sterilized by:	Moist heat
Shelf life:	60 months
Liq Retention Cap/pc	> 4,600g 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	>500 %
Sinking time	<10 s
Sulphated ash	<0,40 %
Thread count warp	100±5 Threads/100 mm
Thread count weft	70±4 Threads/100 mm
Min. breaking load warp	>50 N/5 cm
Min. breaking load weft	>30 N/5cm



Nr and Revision Date:	5 -- 2016/09/11
CE Class:	Ila
CE mark:	CE0120
Directive:	MDD 93/42/ EEC amended by 2007/47/EC

Applicable norms:	EN ISO 13485:2012 ; EN 1041+A1:2013 ; EN ISO 11737-1:2006 ; EN ISO 11737-2:2009 ; EN 556-1:2001 ; EN 14079:2003 ; EN ISO 13726-1 :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 ; ENISO11737-1:2006/AC:2009 ; EN 556-1:2001/AC:2006 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ;
--------------------------	---

Level	Type	Dimension	Stamp	Labels
1	1 Peel-pack	80x100mm	stamped	
2	120 Folding box	084x104x360mm		labeled
3	3240 Carton box	780x380x315mm	stamped	labeled

Important Notes:	NOTE: The complete line of surgical swabs is designed and folded in such a way that all raw cut edges/threads are turned inside and the ultrasonically sealed X-ray is contained inside the multiple folds. 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.
-------------------------	--

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 and skin disinfection, general wound dressing. For swabbing and absorbing blood during surgery.

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	195
--	---	-----

ISSUED BY: Quality Management Department, 2018/09/27

CONFIDENTIAL: The information contained herein is confidential and belongs to Bastos Viegas, s.a. It is provided for specific purposes and in connection with established agreements. It is not permitted disclosure, reproduction, copying or distribution, in whole or in part, for other purposes or to any third parties.