



**Description:** Tracheostomy sponge

<b>Final dimensions:</b>	8 cm x9 cm
<b>Composition:</b>	Polyester, Polyethylene, Polypropylene, Viscose.
<b>Construction:</b>	One face/Uma face
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>Thickness:</b>	2,8 ±20% mm
<b>Sterilized by:</b>	Ethylene Oxide
<b>Shelf life:</b>	60 months
<b>CFU/g</b>	N.A.
<b>Absorption EN 1644-2</b>	> 800 %
<b>Free swell absor. capacity</b>	>22 g/100cm <sup>2</sup>
<b>Size variation</b>	±10 %
<b>Central hole size</b>	12 to 16 mm
<b>Swab cut</b>	3 ± 0,3 cm

STERILE EO



isento  
Latex  
free

isento  
PVC  
free



<b>Nr and Revision Date:</b>	8 -- 1998/05/06
<b>CE Class:</b>	I Steril
<b>CE mark:</b>	CE0120
<b>Directive:</b>	MDD 93/42/ EEC amended by 2007/47/EC

<b>Applicable norms:</b>	EN ISO 13485:2016 ; 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 ISO 13726-2:2002 ; EN ISO 14971:2012 ; EN ISO 10993-1/AC:2010 ; EN ISO 10993-7:2009 ; EN 1422:2014 ; EN ISO 11737-1:2006/AC:2009 ; EN 556-1:2001/AC:2006 ; EN ISO 11135:2014 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ;
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Level	Type	Dimension	Stamp	Labels
1	1 Flexible peel-open pack	134x140mm	stamped	
2	150 Folding box	153x153x360mm - Imp 8		labeled
3	1500 Carton box	780x380x315mm		labeled

<b>Storage instructions</b>	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
<b>Waste instructions</b>	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
<b>Intended use</b>	Intended to be used as a primary dressing for the treatment of light to moderately exuding wounds (minor injuries, including cuts and abrasions; post-surgical wounds and small partial thickness burns). Non-adherent dressing may also be used as a secondary dressing to enhance absorption capacity and/or to extend the time to strike-through. Furthermore, tracheostomy swabs present adequate design with aperture to fit around tubes and drains.

<b>WASTE AND ENVIRONMENT REGULATIONS</b>	Weight (gr) of packing material used in 100 pcs	389
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**ISSUED BY: Quality Management Department, 2019/08/08**