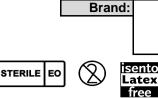


Ref: **4371-002**

Technical Specifications

Description:	Tracheostomy sponge		
Final dimensions:	8 cm x9 cm		
Composition:	Polyester,Polyethylene,Polypropylene,Viscos e.		
Construction:	One face/Uma face		
Latex:	Free		
PVC:	Free		
Re use:	No		
Thickness:	2,8 ±20% mm		
Sterilized by:	Ethylene Oxide		
Shelf life:	60 months		
CFU/g	N.A.		
Absorption EN 1644-2	> 800 %		
Free swell absor. capacity	>22 g/100cm2		
Size variation	±10 %		
Central hole size	12 to 16 mm		
Swab cut	3 ± 0,3 cm		









Nr and Revision Date:	8 1998/05/06		
CE Class:	I Steril		
CE mark:	CE0120		
Directive:	MDD 93/42/ EEC amended by 2007/47/EC		
Applicable norms:	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; ENISO11737-1:2006/AC:2009;	
	EN 556-1:2001/AC:2006 ; EN ISO 11135:201	4 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ;	

Level		Туре	Dimension		Stamp	Labels
1	1	Flexible peel-open pack	134x140mm s		stamped	
2	150	Folding box	153x153x360mm - Imp 8			labeled
3	1500	Carton box	780x380x315mm			labeled

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 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.
Intended use	

WASTE AND ENVIRONMENT REGULATIONS

Weight (gr) of packing material used in 100 pcs

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ISSUED BY: Quality Management Department, 2019/08/08

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