

Ref: 4371-001

Technical Specifications

Brand:



Description: Drainage sponge

Final dimensions:	6 cm x7 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	4,5 to 9 mm	
Swab cut	4 ± 0,4 cm	











Nr and Revision Date:	8 1998/05/06	
	- 1000,000	
CE Class:	I Steril	
CE mark:	CE0120	
Directive:	MDD 93/42/ EEC amended by 2007/47/E	Ö
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 · EI	N ISO 13726-2:2002 · FN ISO 14971:2012 ·

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 11135:2014; ISO 16142-1:2016; EN ISO 15 223-1:2016;

Level		Туре	Dimension	Stamp	Labels
1	1	Flexible peel-open pack	100x125mm	stamped	
2	150	Folding box	104x128x360mm - Imp 8		labeled
3	2700	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, drainage sponges present adequate design with aperture to fit around drains.
Intended use	

WASTE AND ENVIRONMENT REGULATIONS Weight (gr) of packing material used in 100 pcs	257
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ISSUED BY: Quality Management Department, 2019/08/08

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