

Ref: 485-505

Technical Specifications

Brand:



Description: Absorbent dressing pad

Final dimensions:	20 cm x15 cm
Composition:	Cellulose,Cellulose pulp,Polypropylene nonwoven,SSMMS blue PP NW (5 layers).
Construction:	Absorb. pads/Pensos
Latex:	Free
PVC:	Free
Re use:	No
Width variation:	± 5 mm
Length variation:	±10 mm
Colour:	white/ blue
Sterilized by:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Free swell absor. capacity	>65 g/100cm2
Absorption Cap. (ISO 1194	Approx 12,5 ml
Absorption EN 1644-2	Approx. 8 g/g











Nr and Revision Date:	4 1996/10/24	
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 IS

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

Level		Туре	Dimension	Stamp	Labels
1	1	Flexible peel-open pack	134x185mm	stamped	
2	30	Folding box	142x315x192mm	n	labeled
3	240	Carton box	780x285x315mm	n	labeled

Device can be subject to cumulative single, multiple or repeated use or contact up to 30 days (prolonged; type B) with intact, breached or compromised body surface.

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.
	Primary dressing intended for use on moderately to heavily exuding wounds and open drains. Universal use as absorbent pad in general patient care. Ideal for situations where a great capacity of absorption is needed, such as bleedings and chronicle wounds with moderate to high exudation. Secondary dressings for high exuding wounds.
Intended use	

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WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	1053

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

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