

Ref: **485-009**

Technical Specifications

isento PVC free



Description:	Absorbent dressing pad	
Final dimensions: Composition:	<u>30 cm x20 cm</u> Cellulose,Cellulose pulp,Polypropylene nonwoven,SSMMS blue PP NW (5 layers).	
Construction:	Absorb. pads/Pensos	
Latex:	Free	
PVC:	Free	
Re use:	No	
Sterilizable by:	Ethylene Oxyde	
Width variation:	± 5 mm	
Length variation:	± 10 mm	
Colour:	white/ blue	
Shelf life:	120 months	
CFU/g	<10^2	
Free swell absor. capacity		
Absorption Cap. (ISO 1194	Approx 12,5 ml	
Absorption EN 1644-2	Approx. 8 g/g	
Do not sterilize by	Radiation	

	Absorbent pad Perso atsocratite Pansertern association Saugeorground verband	
	Concessa assochente Appalo absochente Absochentade konste 15x25 cm	Absorbent pad
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44	D	

Nr and Revision Date:	4 1996/10/24	
CE Class:	1	
CE mark:	CE	
Directive:	MDD 93/42/EEC amended by 2007/47/EC	
Applicable norms:	EN ISO 13485:2016 ; EN 1041+A1:2013 ; EN	N ISO 11737-1:2006 ; EN ISO 13726-2:2002 ;
	ISO 9073-6:2000 ; EN ISO 14971:2012 ; EN	ISO 10993-1/AC:2010 ; EN 1041:2008 ;
	ENISO11737-1:2006/AC:2009 ; ISO 16142-1::	2016 ;EN ISO 15 223-1:2016 ;

Level		Туре	Dimension	Stamp	Labels	
1	25	Plastic bag			labeled	
2	300	Carton box	790x390x300mm		labeled	
mportant I		Nr pcs/pack subjected to $\pm 3^{\circ}$ Device can be subject to cumula type B) with intact, breached or o	ative single, multiple or repeated use	or contact up to 30	days (prolonged;	
Storage ins	structions	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 inst	ructions	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 dressing for high exuding wounds.				
Intended u	20					

WASTE AND ENVIRONMENT REGULATIONS

Weight (gr) of packing material used in 100 pcs

364

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

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