

Description:	Adhesive drape
Final dimensions:	50 cm x 50 cm x 2 ply
Composition:	Polyethylene film, Viscose nonwoven.
Size variation:	±10 %
Adhesive:	5x50
Latex:	Free
PVC:	Free
Re use:	No
Colour:	green
Sterilized by:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Cleanliness- Microbial	N.A. CFU/100cm ²
Classific. EN13795:2011	HIGH PERFORMANCE
Resist Micro.Penetra.Wet	6,0 IB
Clean particulate matter	<3,5 IPM
Linting	<4.0 log ₁₀ lint count
Resist. liq. penetration	>100 cmH ₂ O
Dry Bursting Strength	>40 kPa
Wet bursting strength	>40 kPa
Dry Tensile strength MD	>50 N/5cm
Dry Tensile strength TD	>20 N/5 cm
Wet Tensile strength MD	>40 N/5cm
Wet Tensile strength TD	>20 N/5cm



Nr and Revision Date:	7 -- 2019/07/22
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 14971:2012 ; EN ISO 10993-1/AC:2010 ; EN ISO 10993-7:2009 ; EN 1422:2014 ; EN 13795+A1:2013 ; EN ISO 11737-1:2006/AC:2009 ; EN 556-1:2001/AC:2006 ; EN ISO 11135:2014 ; EN ISO 15 223-1:2016 ;

Level	Type	Dimension	Stamp	Labels
1	1 Flexible peel-open pack	134x200mm	stamped	
2	70 Folding box	216x151x308mm		labeled
3	700 Carton box	780x225x635mm		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 use	Intended to be used for sterile draping of patients and equipment in operating room, to prevent transfer of infective agents.

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	712
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ISSUED BY: Quality Management Department, 2019/08/08