

Technical Specifications

Brand:



STERILE

EO



isento
Latex
free

isento
PVC
free



Description:	Utility drape
Final dimensions:	45 cm x38 cm
Composition:	Polyethylene film,SB polypropylene nonwoven.
Size variation:	±10 %
Latex:	Free
PVC:	Free
Re use:	No
Colour:	green
Sterilized by:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Classific. EN13795:2011	STANDARD PERFORMANCE
Resist. Micro Penetr. Wet	>2,8 IB
Cleanliness- Microbial	N.A. CFU/100cm^2
Clean particulate matter	<3,5 IPM
Linting	<4,0 log10lint count
Resist. Liq.Penetration	>30 cmH2O
Dry Bursting Strength	>40 kPa
Wet bursting strength	>40 kPa
Dry Tensile Strength	MD>15/CD>25 N/5cm
Wet Tensile Strength	MD>15/CD>25 N/5 cm

Nr and Revision Date:	6 -- 2018/09/13
CE Class:	I Steril
CE mark:	CE0120
Directive:	MDD 93/42/ EEC amended by 2007/47/EC

Applicable norms:	EN ISO 13485:2016 ; EN 1041+A1:2013 ; 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 1422:2014 ;
	EN 13795+A1:2013 ; EN 1041:2008 ; ENISO11737-1:2006/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 Peel-pack	134x200mm	stamped	
2	145 Folding box	216x151x308mm		labeled
3	1450 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	531
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ISSUED BY: Quality Management Department, 2018/11/05