



Description: Utility drape

Final dimensions:	45 cm x75 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.
Class.EN 13795-1:2019	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 cmH ₂ O
Dry Bursting Strength	>40 kPa
Wet bursting strength	>40 kPa
Dry Tensile Strength	MD>40/CD>20 N/5cm
Wet Tensile Strength	MD>40/CD>20 N/5 cm

STERILE EO



isento
Latex
free

isento
PVC
free



Nr and Revision Date:	16 -- 2020/12/18
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	EN_13795_1_2019 ; EN_ISO_13485.2016 ; EN_ISO_13485.2016_AC18 ; EN 556-1.2001_AC.2006 ; ISO_11135.2014 ; ISO_10993-1.2018 ; EN_ISO_11607_1 2017 ; EN_ISO_11607-2.2017 ; ISO_TS_16775.2014 ; ASTM_F1980_16 ; ISO_14644-1:2015 ; ISO_14698_1_2003 ; EN_ISO_14971.2012 ; EN_ISO_15223-1.2016 ; EN_1041.2008_A1.2013 ;
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Level	Type	Dimension	Stamp	Labels
1	1 Flexible peel-open pack	134x200mm		
2	90 Folding box	216x151x308mm		labeled
3	900 Carton box	780x225x635mm		labeled

Important Notes:	The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage.
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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	As covering drape to prevent transfer of infective agents in surgical context.

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	634
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ISSUED BY: Quality Management Department, 2020/12/18