



**Description:** Utility drape

<b>Final dimensions:</b>	45 cm x75 cm
<b>Composition:</b>	Polyethylene film,SB polypropylene nonwoven.
<b>Size variation:</b>	±10 %
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>Colour:</b>	green
<b>Sterilized by:</b>	Ethylene Oxide
<b>Shelf life:</b>	60 months
<b>CFU/g</b>	N.A.
<b>Class.EN 13795-1:2019</b>	STANDARD PERFORMANCE
<b>Resist. Micro Penetr. Wet</b>	>2,8 IB
<b>Cleanliness- Microbial</b>	N.A. CFU/100cm <sup>2</sup>
<b>Clean particulate matter</b>	<3,5 IPM
<b>Linting</b>	<4,0 log10lint count
<b>Resist. Liq.Penetration</b>	>30 cmH <sub>2</sub> O
<b>Dry Bursting Strength</b>	>40 kPa
<b>Wet bursting strength</b>	>40 kPa
<b>Dry Tensile Strength</b>	MD>40/CD>20 N/5cm
<b>Wet Tensile Strength</b>	MD>40/CD>20 N/5 cm

STERILE EO



isento  
Latex  
free

isento  
PVC  
free



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

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.

**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.

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