

Description: Surgical drape

Final dimensions:	50 cm x 60 cm x 2 ply
Composition:	Polyethylene film, Viscose nonwoven.
Size variation:	±10 %
Latex:	Free
PVC:	Free
Re use:	No
Sterilized by:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Cleanliness- Microbial	N.A. CFU/100cm ²
Class.EN 13795-1:2019	HIGH PERFORMANCE
Resist Micro.Penetra.Wet	6,0 IB
Clean particulate matter	<3,5 IPM
Linting	<4.0 log10 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:	9 -- 2020/09/07
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 ; EN_ISO_11737-2.2009 ; ISO_11135.2014 ; EN_ISO_11607_1 2017 ; ISO_10993-1.2018 ; EN_ISO_11607-2.2017 ; ASTM_F1980_16 ; 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	60 Folding box	216x151x308mm		labeled
3	600 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	Intended to be used for sterile draping of patients and equipment in operating room, to prevent transfer of infective agents.

Non-harmonized symbols used in article labeling  plies

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	771
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ISSUED BY: Quality Management Department, 2020/12/17