

Product Specification

Ref: **488-104**

Alias: 488999104

Brand:



DRQ 14/21 REV.03 2026/06/18

Description: Surgical Drape

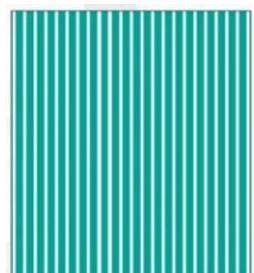
Final dimensions:	100 cm x150 cm x 2 plies
Composition:	Polyethylene film,Viscose nonwoven.
Size variation:	±5 %
Construction:	Drapes LA
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	green
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g:	N.A.
Class.EN 13795-1:2019:	HIGH PERFORMANCE
Resist Micro.Penetra.Wet:	6,0 IB
Linting:	<4.0 log10lint count
Resist. liq. penetration:	>100 cmH2O
Cleanliness- microbial:	N.A. CFU/100cm ²
Sterility Assur. Level SAL:	≤10 ⁻⁶
Flammability (16CFR1610):	Class 3
Flammability-Prim.ignition:	I4 21 (ignition<4s)
Flammability-Prim.penetration:	P4 21(<1s to 10mW)
Dry Bursting Strength:	>120 kPa
Wet Bursting strength:	>100 kPa
Dry Tensile strength MD:	≥60 N/5cm
Dry Tensile strength TD:	≥20 N/5 cm
Wet Tensile strength MD:	≥45 N/5cm
Wet Tensile strength TD:	≥20 N/5cm

STERILE EO



isento
Latex
free

isento
PVC
free



2E

Nr and Revision Date:	21 -- 2026/09/01
CE Class:	IEE
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	16CFR Part 1610 ; ISO 11810:2015 ; ISO TR 24971:2020 ; ISO TR 20416:2020 ; EN 17141:2020 ; ISO 14698-2:2003 ; ISO 8601-1:2019 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; EN ISO 10993-18:20 AMD1:23 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; ASTM F1886/F1886M-16 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; ISTA Standard 3E ; ASTM F1980-21 ; EN 13795-1:2019 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2020 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; ISO 14644-5:2004 ; ISO 14698-1:2003 ; EN ISO 14644-1:2015 ; ISTA Standard 2A ; ISO 2759:2014 ; ISO 3037:2022 ; EN ISO 15223-1:2021 ; EN ISO 20417:2026 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019-Not applicable ; EN ISO 10993-7:2008 ; EN ISO 11607-1:2020 ; EN ISO 11607-2:2020 ; CEN ISO TS 16775 2021 ;
GMDN:	47783 - Patient surgical drape, single-use
EMDN:	T020199 - SURGICAL DRAPES - OTHER

PACKING

Level	Units	Type	Dimension	Stamp	Labels
 22	1 1	Flexible peel-open pack	200x290mm		
 20	2 20	Carton box	312x213x247mm		labeled
 20	3 120	Carton box	786x231x641mm		labeled

Basic UDI	56056221119009KP
	EAN 1th level/nivel:05605622212777
	EAN 2th level/nivel:05605622412771
	EAN Carton Box/Caixa:05605622012773

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 purpose:	As covering drape to prevent transfer of infective agents in surgical context.

Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility.

Non-harmonized symbols used in article labeling		Nr of plies
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Environment - Packaging waste	Weight(gr) of packing material used in 100 pcs	2528	
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ISSUED BY: Quality Management Department, 2026/09/02

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