

Product Specification

Ref: **4541-013**

Alías: 454199013

Brand:



DRQ 14/21 REV.02 2024/09/20

Description:	Impermeable protection sheet
Final dimensions:	95 cm x3 m
Composition:	Polyester,Polyethylene film,SB Polypropylene Non woven.
Construction:	SB15/PE22
Latex:	Present
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	green
Shelf life:	120 months
CFU/g	<10 ²
Fluorescence	conform
Dry Tensile strength MD	>45 N/5cm
Dry Tensile strength TD	>20 N/5 cm
Resist Micro.Penetra.Wet	6.0 IB
Resist. liq. penetration	>65 cmH ₂ O
Resist Micro Penetr.Dry	<300 CFU
Absorption Capacity	>150 %
Do not sterilize by	Moist heat
Size variation	±5 %



Nr and Revision Date:	31 -- 2025/03/07
CE Class:	I
CE mark:	CE
Compliance with:	MDR (EU) 2017/745
Applicable standards:	EN ISO10993-1:09 AC:10 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; EN ISO 10993-18:2009 ; EN ISO 20417:2021 ; EN ISO 15223-1:2021 ; ICH Q1A (2003) ; ISTA Standard 2A ; ASTM D4332 01 ; ASTM D4169-22 ; ISO 10993-18:2020 AMD1:2022 ; ISO TR 24971:2020 ; ISO TR 20416:2020 ; ISO 2859 1:1999 ; EN 17141:2020 ; ISO 14698-2:2003 ; ISO 8601-1:2019 ; IEC TR 62366-2:2016 ; IEC 62366-1:2015 A1:2020 ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 11737-1:2018 ; EN ISO 13485:2016 A11:2021 ; ISO 14698-1:2003 ; EN ISO 11737-1:18 A1:21 ; ASTM F1980 16 ; EN ISO 14971:2012 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO 15223-1:2016 ; EN 1041:2008 A1:2013 ; ISO 2759:2014 ; ISO 3037:2013 ; ASTM D7386-16 ;
GMDN:	61048 - Patient examination / treatment drape, single-use

Important Notes:	With elastic all around to keep tight hold on. Waterproof
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PACKING					
Level	Units	Type	Dimension	Stamp	Labels
 1	40	Plastic bag	1200x900x000mm		labeled
 2	40	Carton box	786x386x321mm		labeled

Basic UDI	56056221009016JU
	EAN 1th level/nivel:05605622070162
	EAN Carton Box/Caixa:25605622070166

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 a protective cover to prevent transfer of infective agents.
	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

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	2074
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ISSUED BY: Quality Management Department, 2025/04/01

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