


# 15S01/BL | IsoDrapeS | Technical data sheet

Importer:	DACH Schutzbekleidung GmbH & Co. KG				
Product:	IsoDrapeS				
REF:	15S01/BL				
Classification:	<ul style="list-style-type: none"><li>▪ According to the classification criteria of MDD 93 /42 /EWG, Annex IX, this medical device is classified as Class Is.</li><li>▪ Is manufactured according to the requirement EN ISO 13485:2016.</li><li>▪ The product is used as a sterile product.</li></ul>				
Standard:	BS EN 13795-1	Surgical gowns and drapes. Requirements and test methods Surgical drapes and gowns.			
Materials:	The low-linting and soft surgical drape is made of blue absorbent 50 g/m2 non-woven fabric.				
Sterilisation:	Ethylene oxide sterilisation				
Product description:	<ul style="list-style-type: none"><li>▪ The IsoDrapeS product is a standard sterile surgical drape that is used to create a sterile area during surgical procedures. The purpose of a surgical drape is to prevent the spread of fluids and bacteria from non-sterile to sterile areas and to protect the patient from contamination.</li><li>▪ The medical folding allows easy unpacking.</li><li>▪ The surgical drape is sterile.</li><li>▪ The surgical drape is free of natural latex.</li><li>▪ The surgical drape is disposable and therefore maintenance-free, offering increased safety and protection. The signal color coding saves time and effort.</li><li>▪ Ideal for use in the operating room.</li></ul>				
Product performance:	Physical and biological properties				
	Testing	Standard	Unit	Request	Test result (mean value)
	Germ penetration (dry)	EN ISO 22610	CFU	For "Critical Area" not required - for "Less Critical Area" ≤ 300	0
	Germ penetration (wet)	EN ISO 22610	I <sub>B</sub>	≥ 6	6

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	Microbiological purity/germ contamination	EN ISO 11737-1	CFU*/ 100 cm²	≤ 300	< 24
	Particle release	EN ISO 9073-10	Log <sub>10</sub> (Number of fibre fragments)	≤ 4,0	2,64
	Liquid penetration	EN ISO 811	cm H <sub>2</sub> O	≥ 100	100
	Bursting strength (dry)	EN ISO 13938-1	kPa	≥ 40	136,3
	Bursting strength (wet)	EN ISO 13938-1	kPa	≥ 40	<ul style="list-style-type: none"><li>▪ Material: 91,6</li><li>▪ Seam: 131,6</li></ul>
	Tear strength (dry)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none"><li>▪ Material length: 91,6</li><li>▪ Material width: 53,26</li></ul>
	Tear strength (wet)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none"><li>▪ Material length: 92,1</li><li>▪ Material width: 57,34</li></ul>
	*CFU = Colony forming units				
Sizes and dimensions:	Length (cm)			Width (cm)	
	50			60	
	75			90	
Colour:	Light blue				
Packaging and variants:	Packaging		Quantity		
	REF		15S01/BL (50X60)		15S01/BL (75X90)
	Bag		1 pc.		1 pc.
	Carton		350 pcs.		220 pcs.
	Euro pallet		12.600 pcs (36 cartons)		7.920 pcs. (36 cartons)

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<b>GTIN:</b>	Bag	4049825005339	4049825005346
	Carton	4049825505327	4049825505334
<b>Application:</b>	<ul style="list-style-type: none"> <li>▪ Suitable for single use</li> <li>▪ Used gowns are considered contaminated</li> <li>▪ Do not clean or disinfect</li> <li>▪ Product is sterile</li> </ul>		
<b>Storage:</b>	<ul style="list-style-type: none"> <li>▪ The storage environment must be corrosion-free, dry, protected from sunlight, well ventilated and clean.</li> <li>▪ The product must be handled with care during transport and handling.</li> </ul>		
<b>Environmental compatibility and disposal:</b>	<ul style="list-style-type: none"> <li>▪ For single use only.</li> <li>▪ Used surgical drapes are considered contaminated</li> <li>▪ Must follow sterile procedure.</li> <li>▪ After use it should be treated as a biohazard.</li> </ul>		
<b>Manufacturer:</b>	Jiangsu Medplus Non-Woven Manufacturer Co., Ltd. Industrial Park, Jiangdu Bridge, Yangzhou, 225211 Jiangsu P.R. China		
<b>EU Representative:</b>	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg, Germany		