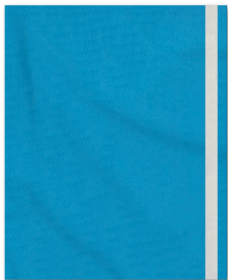


Importer:	DACH Schutzbekleidung GmbH & Co. KG				
Product:	IsoDrapeS (selbstklebend/adhesive)				
REF:	15S02BL				
Classification:	<ul style="list-style-type: none">▪ According to the classification criteria of MDD 93 /42 /EWG, Annex IX, this medical device is classified as Class Is.▪ Is manufactured according to the requirement EN ISO 13485:2016.▪ The product is used as a sterile product.				
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 consists of blue absorbent 50 g/m2 non-woven fabric and a 5 cm wide double-sided adhesive tape.				
Sterilisation:	Ethylene oxide sterilisation				
Product description:	<ul style="list-style-type: none">▪ The product IsoDrapeS (self-adhesive) is a self-adhesive 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.▪ The medical fold allows easy removal.▪ The surgical drape is sterile.▪ The surgical drape is self-adhesive thanks to the 5 cm wide double-sided tape.▪ The surgical drape is free of natural latex.▪ The surgical drape is disposable and therefore maintenance-free, offering increased safety and protection. The signal color coding saves time and effort.▪ Ideal for use in the operating room.				
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 _B	≥ 6	6
	Microbiological purity/germ contamination	EN ISO 11737-1	CFU*/ 100 cm²	≤ 300	< 24

	Particle release	EN ISO 9073-10	Log ₁₀ (Number of fibre fragments)	≤ 4,0	2,64
	Liquid penetration	EN ISO 811	cm H ₂ 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">▪ Material: 91,6▪ Seam: 131,6
	Tear strength (dry)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none">▪ Material length: 91,6▪ Material width: 53,26
	Tear strength (wet)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none">▪ Material length: 92,1▪ Material width: 57,34
	*CFU = Colony forming units				
Sizes and dimensions:	Length (cm)			Width (cm)	
	50			60	
	75			90	
Colour:	Light blue				
Packaging and variants:	Packaging	Amount			
	REF	15S02BL (50X60)		15S02BL (75X90)	
	Bag	1 pc.		1 pc.	
	Carton	350 pcs.		190 pcs.	
	Euro palet	12.600 pcs (36 cartons)		6.840 pcs (36 cartons)	
	Bag	4049825005353		4049825005360	
	Carton	4049825505341		4049825505358	
Application:	<ul style="list-style-type: none">▪ Suitable for single use▪ Used gowns are considered contaminated▪ Do not clean or disinfect▪ Product is sterile				

Storage:	<ul style="list-style-type: none"> ▪ The storage environment must be corrosion-free, dry, protected from sunlight, well ventilated and clean. ▪ The product must be handled with care during transport and handling.
Environmental compatibility and disposal:	<ul style="list-style-type: none"> ▪ For single use only. ▪ Used surgical drapes are considered contaminated ▪ Must follow sterile procedure. ▪ After use it should be treated as a biohazard.
Manufacturer:	Jiangsu Medplus Non-Woven Manufacturer Co., Ltd. Industrial Park, Jiangdu Bridge, Yangzhou, 225211 Jiangsu P.R. China
EU Representative:	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg, Germany