


Importer:	DACH Schutzbekleidung GmbH & Co. KG				
Product:	EcoCoat Splash S (Reinforced Surgical gown)				
REF:	4S02BL				
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:	Reinforced surgical gown made of 5-layer polypropylene with antistatic and liquid resistant material. PE laminated.				
Sterilisation:	Ethylene oxide sterilisation				
Product description:	<ul style="list-style-type: none"><li>▪ The EcoCoat Splash S is a reinforced sterile surgical gown with a cellulose towel (50 gr/m2) in 30x40 cm and a cover made of SMS (25 gr/m2) which offers protection against the penetration of liquids and bacteria.</li><li>▪ The low lint and abrasion resistant gown is ultrasonically welded and is made partly of 35 gr/ m2 PP-SMS nonwoven microfiber fabric plus breathable white 43 gr/m2 PE-laminated cellulose.</li><li>▪ The medical folding allows easy and user-oriented removal of the product and thus it supports dressing.</li><li>▪ The reinforced surgical gown has the opening on the back and for closing it has two tie bands on the collar and two tie belts as well as knitted cuffs.</li><li>▪ The reinforced surgical gown is natural latex free.</li><li>▪ The reinforced surgical gown is single-use maintenance-free providing increased safety and protection. Signal color coding saves time and effort.</li><li>▪ Ideal for applications 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	8,1
	Germ penetration (wet)	EN ISO 22610	I <sub>B</sub>	≥ 2,8	<ul style="list-style-type: none"><li>▪ Material: 6</li><li>▪ Seam: 6</li></ul>

	Microbiological purity/germ contamination	EN ISO 11737-1	CFU*/ 100 cm²	≤ 300	< 6
	Particle release	EN ISO 9073-10	Log <sub>10</sub> (Number of fibre fragments)	≤ 4,0	<ul style="list-style-type: none"><li>▪ Material: 2,51</li><li>▪ Seam: 2,36</li></ul>
	Liquid penetration	EN ISO 811	cm H <sub>2</sub> O	≥ 20	> 100
	Bursting strength (dry)	EN ISO 13938-1	kPa	≥ 40	<ul style="list-style-type: none"><li>▪ Material: 137,1</li><li>▪ Seam: 210</li></ul>
	Bursting strength (wet)	EN ISO 13938-1	kPa	≥ 40	<ul style="list-style-type: none"><li>▪ Material: 145,6</li><li>▪ Seam: 221,2</li></ul>
	Tear strength (dry)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none"><li>▪ Material length: 27,98</li><li>▪ Material width: 44,32</li><li>▪ Seam: 48</li></ul>
	Tear strength (wet)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none"><li>▪ Material length: 26,16</li><li>▪ Material width: 45,25</li><li>▪ Seam: 57,26</li></ul>
	*CFU = Colony forming units				
	The tests were carried out on the material of the gown. The seams and knitted cuffs were not tested.				
Sizes and dimensions:	Size	Length (cm)		Width (cm)	
	M	115		145	
	L	125		150	
	XL	135		160	
Colour:	Blue				
Packaging and variants:	Packaging	Amount			
	Bag	1 pcs.			
	Carton	50 pcs.			
	Euro palet	1000 pcs.			

GTIN:	4S01BL-M	4049825005278
	4S01BL-L	4049825005315
	4S01BL-XL	4049825005322
Application:	<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>	
Storage:	<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>	
Environmental compatibility and disposal:	<ul style="list-style-type: none"> <li>▪ For single use only.</li> <li>▪ Must follow sterile procedure.</li> <li>▪ After use it should be treated as a biohazard.</li> </ul>	
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	