


# REF 4S02/BL | EcoCoat Splash S | (Reinforced Surgical gown) | Technical data sheet

Importer:	DACH Schutzbekleidung GmbH & Co. KG			
Product:	EcoCoat Splash S (Reinforced Surgical gown)			
REF:	4S02/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:	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

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	Germ penetration (dry)	EN ISO 22610	CFU	For "Critical Area" not required - for "Less Critical Area" $\leq 300$	8,1
	Germ penetration (wet)	EN ISO 22610	$I_B$	$\geq 2,8$	<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 cm <sup>2</sup>	$\leq 300$	< 6
	Particle release	EN ISO 9073-10	Log <sub>10</sub> (Number of fibre fragments)	$\leq 4,0$	<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	$\geq 20$	> 100
	Bursting strength (dry)	EN ISO 13938-1	kPa	$\geq 40$	<ul style="list-style-type: none"> <li>Material: 137,1</li> <li>Seam: 210</li> </ul>
	Bursting strength (wet)	EN ISO 13938-1	kPa	$\geq 40$	<ul style="list-style-type: none"> <li>Material: 145,6</li> <li>Seam: 221,2</li> </ul>
	Tear strength (dry)	EN 29073-3	N	$\geq 20$	<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	$\geq 20$	<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)	

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	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:	M	4049825005278	
	L	4049825005315	
	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		