


Importer:	DACH Schutzbekleidung GmbH & Co. KG				
Product:	EcoCoat Splash S (Reinforced Surgical gown)				
REF:	4S02/BL				
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:	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">▪ 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.▪ 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.▪ The medical folding allows easy and user-oriented removal of the product and thus it supports dressing.▪ 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.▪ The reinforced surgical gown is natural latex free.▪ The reinforced surgical gown is single-use maintenance-free providing increased safety and protection. Signal color coding saves time and effort.▪ Ideal for applications 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	8,1

	Germ penetration (wet)	EN ISO 22610	I_B	$\geq 2,8$	<ul style="list-style-type: none">▪ Material: 6▪ Seam: 6
	Microbiological purity/germ contamination	EN ISO 11737-1	CFU*/ 100 cm²	≤ 300	< 6
	Particle release	EN ISO 9073-10	Log ₁₀ (Number of fibre fragments)	$\leq 4,0$	<ul style="list-style-type: none">▪ Material: 2,51▪ Seam: 2,36
	Liquid penetration	EN ISO 811	cm H ₂ O	≥ 20	> 100
	Bursting strength (dry)	EN ISO 13938-1	kPa	≥ 40	<ul style="list-style-type: none">▪ Material: 137,1▪ Seam: 210
	Bursting strength (wet)	EN ISO 13938-1	kPa	≥ 40	<ul style="list-style-type: none">▪ Material: 145,6▪ Seam: 221,2
	Tear strength (dry)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none">▪ Material length: 27,98▪ Material width: 44,32▪ Seam: 48
	Tear strength (wet)	EN 29073-3	N	≥ 20	<ul style="list-style-type: none">▪ Material length: 26,16▪ Material width: 45,25▪ Seam: 57,26
	*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:	M	4049825005278
	L	4049825005315
	XL	4049825005322
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. ▪ 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	