



Product:	MediClassic Splash	
Trademark:	SAFE®	
REF:	208G	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	Class I, based on the Medical Devices Regulation (EU) 2017/745 MDR, Annex VIII; UMDNS Code: 12-458			
Protection class:	Type IIR (liquid resistant), tested according to EN 14683:2019 for medical face masks.			
Materials:	<ul style="list-style-type: none">▪ Outer side: liquid-repellent polypropylene nonwoven▪ Inner side: skin-friendly, hypoallergenic polypropylene nonwoven▪ Filter medium: microfiber made of polypropylene▪ Ear Loops: Polyester and elastane, free from natural rubber▪ Nose piece: PE coated wire▪ Shield: anti-fog with side flaps, vision is not distorted			
Product description:	<p>High-quality, anatomically shaped, 3-layer face mask with easy-to-mold nose piece, free from natural latex. The inside and outside are made of physiologically safe plasticizer-free polypropylene nonwoven.</p> <p>The filter medium consists of microfiber nunwoven. The mask ultrasonically welded using state-of-the-art technology.</p> <p>The non-reflective, anti-fog eye shield with side flaps protects against splashes of liquids.</p>			
Product performance:	<i>Product performance according to EN 14683:2019+AC:2019</i>			
	Testing	Performance class	Requirement	Test result
	Bacterial filtration efficiency (BFE), (%)	Type IIR	≥ 98	99,9
	Pressure difference (Pa/cm²)		< 60	33,3
	Splash resistance pressure (kPa)		≥ 16,0	16
	Microbial cleanliness (CFU/g)		≤ 30	≤ 5
	*CFU = colony forming units.			

Colour:	Green	
Dermatological compatibility:	No contraindications.	
Size:	17,5 x 9,5/17 cm	
Packaging and variants:	Packaging	Quantity
	Dispenser box	25 pcs.
	Shipping carton	400 pcs.
GTIN:	208G	4049825006855
Use:	<p>All materials used are free of irritants, odorless and suitable for medical purposes.</p> <p>Conform to the biological compatibility ISO 10993.</p> <p>The mask is worn by healthcare professionals around the patient to protect the patient.</p>	
Service life:	Single use	
Storage:	<p>Store without direct sunlight, dry in original packaging, see also packaging.</p> <p>If the storage conditions are observed, the product has a storage life of 5 years.</p>	
Environmental sustainability and disposal:	<p>The product can be thermally recycled or disposed of in landfills without releasing toxic substances.</p> <p>In the case of contaminated products, the type and extent of contamination determine the disposal, and the applicable laws and regulations must be observed.</p>	
Indication:	 Non sterile	