Product Data Sheet



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



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:	 Outer side: liquid-repellent polypropylene fleece Inner side: skin-friendly, hypoallergenic polypropylene fleece Filter medium: microfiber made of polypropylene Rubber band: high quality polyurethane, latex free and soft Noseband: PE coated wire Shield: anti-fog with side flaps, vision is not distorted 		
Product description:	Latex-free, high-quality, anatomically shaped, 3-layer face mask with easy-to-mold nosepiece, the inside and outside are made of physiologically safe plasticizer-free polypropylene fleece. The filter medium consists of microfiber fleece ultrasonically welded. The non-reflective, anti-fog eye shield protects against splashes of liquids. With side protection. Free of latex and phthalates.		

Product performance:	Product performance according to EN 14683:2019+AC:2019				
	Testing	Performance class	Requirement	Test result	
	Bacterial filtration efficiency (BFE), (%)	Type IIR	≥ 98	99,9	
	Pressure difference (Pa/cm²)		< 60	33,3	
	Spray resistance pressure (kPa)		≥ 16,0	16	

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	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:	2086		4049825006855			
Use:	All materials used are free of irritants, odorless and suitable for medical purposes. Conform to the biological compatibility ISO 10993. The mask is worn by healthcare professionals around the patient to protect the patient.					
Service life:	Single use					
Storage:	Store without direct sunlight, dry in original packaging, see also packaging. If the storage conditions are observed, the product has a storage life of 5 years.					
Environmental sustainability and disposal:	The product can be thermally recycled or disposed of in landfills without releasing toxic substances. In the case of contaminated products, the type and extent of contamination determine the disposal, and the applicable laws and regulations must be observed.					
Indication:	Non sterile					