

Product:	MediClassic Splash	
Trademark:	SAFE®	
REF:	209G	
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:	- Outer side: liquid-repellent polypropylene nonwoven - Inner side: skin-friendly, hypoallergenic polypropylene nonwoven - Filter medium: polypropylene microfiber - Ties: polypropylene nonwoven - Nose piece: PE coated wire - Shield: anti-fog with side flaps, vision is not distorted			
Product description:	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. The filter medium consists of microfiber nunwoven. The mask ultrasonically welded using state-of-the-art technology. The non-reflective, anti-fog eye shield with side flaps protects against splashes of liquids.			
Product services:	<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
	Spray 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.		
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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.			
Usage:	Single use			
Storage:	Store dry in original packaging without direct sunlight. (see packaging) If the storage conditions are observed, the product has a storage life of 5 years. (see labeling on the product)			
Environmental sustainability and disposal:	In the case of contaminated products, the type and extent of contamination determines the disposal, and the applicable laws and regulations of the relevant country must be followed. A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.			
Indication:	 Non sterile.			