Product Data Sheet



Product:	MediComfort Antifog	
Trademark:	SAFE®	
REF:	2236	
Manufacturer:	DACH Schutzbekleidung GmbH හ Co. KG	

Classification:	Class I, based on the Medical Devices Regulation (EU) 2017/745 MDR, Annex VII; UMDNS Code: 12-458				
Performance class:	Type II R (liquid resistant), tested according to EN 14683:2019 for medical face masks.				
Materials:	 Outside: liquid repellent polypropylene fleece Inner side: skin-friendly, allergen-free polypropylene fleece Filter medium: polypropylene microfiber Anti-fogging strips: coated polypropylene fleece Straps: skin-friendly, non-allergenic polypropylene fleece Noseband: PE coated wire 				
Product description:	Latex-free, high-quality, anatomically shaped face mask with easy-to-mold nosepiece, inside and outside made of physiologically safe plasticizer-free polypropylene fleece. The filter medium is a special microfiber fleece manufactured in the meltblown process, welded together in the ultrasonic process. There is an anti-fog strip on the nosepiece, which prevents the passage of moist breathing air.				

Product performance:	Product performance according to EN 14683:2019+AC:2019				
	Testing	Performance class	Requirement	Test result	
	Bacterial filtration efficiency (BFE), (%)	Typ IIR	≥ 98	99,9	
	Pressure difference (Pa/cm²)		< 60	56,5	
	Spray resistance pressure (kPa)		≥ 16,0	16	



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	Microbial cleanliness]	≤ 30	≤ 25,6	
	(CFU/g)		2.30	225,0	
Dermatological compatibility:	No contraindications				
Colour:	Green striped				
Packaging and variants:	Packaging		Quantity		
	Dispenser box		50 pcs.		
	Shipping carton		600 pcs.		
GTIN:	223G		4049825000211		
Use:	All materials used are free of irritants, odorless and suitable for medical purposes.				
	Conform to the biological compatibility ISO 10993.				
	The special inner material makes the mask suitable for permanent use and provides exc protection for both healthcare professionals and patients.				
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	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.				
disposal:	A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.				
Indication:	Non sterile.				
	NON				

