Product Data Sheet



Product:	MediComfort Excel	
Trademark:	SAFE®	
REF:	2216	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	Class I of Regulation (EU) 2017/745 on medical devices; UMDNS Code: 12-458	
Protection class:	Type II R (liquid resistant), tested according to EN 14683:2019 for surgical masks.	
Materials:	 Outside: liquid-repellent polypropylene fleece Inner side: especially soft and skin-friendly, allergen-free polypropylene fleece Filter medium: microfiber made of polypropylene Straps: skin-friendly, allergy-free polypropylene fleece Noseband: PE coated wire 	
Product Description:	Latex-free, high-quality, anatomically shaped face mask with easy-to-mold nosepiece. The inside and outside are made of physiologically harmless unplasticized polypropylene fleece. The filter medium is a special microfiber fleece manufactured in the meltblown process, welded together in the ultrasonic process.	

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/cm ²)	-	< 60	56,5	
	Spray resistance pressure (kPa)	_	≥ 16,0	16	
	Microbial cleanliness (CFU/g)		≤ 30	≤ 25,6	



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Dermatological compatibility:	No intolerance reactions		
Colour:	Green striped		
Packaging and variants:	Packaging Quantity		
	Dispenser box	50 pcs.	
	Shippping carton	1.000 pcs.	
GTIN:	221G	4049825000198	
Use:	All materials used are free of irritants, odorless and suitable for medical purposes. The mask is suitable for permanent use in clean rooms, e.g. operating rooms, pharmaceuticals, food and electronics, and provides excellent protection.		
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.		

