

Product:	MediClassic Excel	
Trademark:	SAFE®	
REF:	2101G 2101B	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	Class I, based on Medical Device Regulation (EU) 2017/745 MDR, Annex VIII; UMDNS Code: 12-458.			
Protection class:	Type II R (liquid resistant), tested according to EN 14683:2019 for medical face masks.			
Product description:	Latex-free, high-quality, anatomically shaped face mask with easily moldable nosepiece. The inside and outside are made of physiologically harmless unplasticized polypropylene fleece, the filter medium is made of special microfiber fleece produced in the meltblown process, welded together in the ultrasonic process. Conforms to the HACCP concept.			
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	55
	Spray resistance pressure (kPa)		≥ 16,0	16
	Microbial cleanliness (CFU/g)		≤ 30	≤ 19,4
Dermatological compatibility:	No contraindications.			
Colours:	Green, Blue			
Packaging and variants:	Packaging		Quantity	
	Dispenser box		50 pcs.	
	Shipping carton		1.000 pcs.	
GTIN:	2101B		4049825002338	

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Use:	All materials used are free of irritants, odorless and suitable for medical purposes. Comply with the biological compatibility ISO 10993. By wearing the mask, the wearer protects his environment.	
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. 	