

Product:	Model D Loop	 
REF:	216	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	Class I, based on Medical Device Regulation (EU) 2017/745 MDR, Annex VIII; UMDNS Code: 12-458.			
Performance class:	Type IIR (liquid resistant), tested according to EN 14683:2019+AC:2019 for medical face masks.			
Materials:	▪ Outside: polypropylene spunbonded fabric ▪ Inner side: skin-friendly polypropylene spunbonded fabric ▪ Filter medium: polypropylene microfiber ▪ Ear loops: soft polypropylene and elastane ▪ Noseband: HDPE coated wire			
Product description:	Medical face mask type IIR »Made in Germany«. Latex-free, hypoallergenic, anatomically shaped face mask with easy-to-mold nosepiece. The inside and outside are physiologically safe and plasticizer-free. With ear loops for easy donning and doffing.			
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
	Pressure difference (Pa/cm²)		< 60	25
	Spray resistance pressure (kPa)		≥ 16,0	16,0
	Microbial cleanliness (CFU/g)		≤ 30	≤ 12
	*CFU = Colony Forming Units			

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.	
Colours:	Blue, Lilac, Pink, Orange	
Packaging and variants:	Packaging	Quantity
	Dispenser box	50 pcs.
	Shipping carton	1100 pcs.
GTIN:	216/B	4049825006183
	216/FL	4049825007043
	216/RO	4049825007012
Storage:	Store in a dry place without direct sunlight in the original packaging (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. 	