



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:	<ul style="list-style-type: none"> 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:	<p>Medical face mask type IIR »Made in Germany«.</p> <p>Latex-free, hypoallergenic, anatomically shaped face mask with easy-to-mold nosepiece.</p> <p>The inside and outside are physiologically safe and plasticizer-free.</p> <p>With ear loops for easy donning and doffing.</p>

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:	<p>All materials used are free of irritants, odorless and suitable for medical purposes.</p> <p>Conform to the biological compatibility ISO 10993.</p> <p>The mask is worn by healthcare professionals around the patient to protect the patient.</p>	
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
	216/OR	4049825007036
Storage:	<p>Store in a dry place without direct sunlight in the original packaging (see packaging).</p> <p>If the storage conditions are observed, the product has a storage life of 5 years (see labeling on the product).</p>	
Environmental sustainability and disposal:	<p>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.</p> <p>A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.</p>	
Indication:	<p>Non sterile.</p> 