## **Product Data Sheet**



Product:	MediPro Loop		
Trademark:	SAFE®		
REF:	2108		
Manufacturer:	DACH Schutzbekleidung GmbH හ 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 for medical face masks		
Materials:	<ul> <li>Outside: liquid-repellent polypropylene fleece</li> <li>Inner side: especially smooth and skin-friendly polypropylene fleece</li> <li>Filter medium: microfiber made of polypropylene</li> <li>Ear loops: soft textile rubber band, free of natural latex</li> <li>Noseband: metal wire, coated with synthetic material</li> </ul>		
Product description:	Latex-free, hypoallergenic, high-quality, anatomically shaped face mask with easily modelable nosepiece.  The newly developed skin-friendly inner fleece does not lint and, combined with particularly fluffy ear		
	loops, guarantees a high level of wearing comfort.		
	The filter medium consists of special microfiber fleece, which provides an efficient barrier against bacteria.		
	The entire mask is ultrasonically welded using the latest technology.		
	Complies with 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	24	
	Spray resistance pressure (kPa)		≥ 16,0	16,0	
	Microbial cleanliness (CFU/g)		≤ 30	≤3	
Colours:	Green, Blue				

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Dermatological compatibility:	No contraindications.		
Packaging and variants:	Packaging	Quantity	
	Dispenser box	50 pcs.	
	Shipping carton	2.000 pcs.	
GTIN:	2108/G	4049825006428	
	2108/B	4049825006442	
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.		
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).c		
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.		