



Product:	MediPro Loop	
Trademark:	SAFE®	
REF:	2108	
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 for medical face masks			
Materials:	<ul style="list-style-type: none">▪ Outside: liquid-repellent polypropylene nonwoven▪ Inner side: especially smooth and skin-friendly polypropylene nonwoven, as far as possible without protruding fibre ends▪ Filter medium: microfiber made of polypropylene▪ Ear loops: soft textile rubber band, free from natural latex▪ Noseband: metal wire, coated with synthetic material			
Product description:	<p>Natural latex free, hypoallergenic, high-quality, anatomically shaped face mask with exceptional high wearing comfort and easily modelable nosepiece.</p> <p>The newly developed skin-friendly inner layer does not lint and, avoids the adhesion of the nonwoven fibers and the nonwoven fabric to the facial hair and skin.</p> <p>The filter medium consists of special microfiber nonwoven, which provides an efficient barrier against bacteria.</p> <p>The entire mask is ultrasonically welded using newest state of the art technology.</p> <p>Complies with the HACCP concept.</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	99,9
	Pressure difference (Pa/cm²)		< 60	24
	Spray resistance pressure (kPa)		≥ 16,0	16,0
	Microbial cleanliness (CFU/g)		≤ 30	≤ 3
Colours:	Green, Blue			

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:	<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>	
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>	