## **Product Data Sheet**



Product:	Surgical mask	
REF:	202	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	Class I, based on the Medical Devices Regulation (EU) 2017/745 MDR, Annex VIII; UMDNS Code: 12-458			
Protection class:	Type II, tested according to EN 14683:2019+AC:2019 for medical face masks			
Materials:	<ul> <li>Outer layer: Polypropylene</li> <li>Inner layer: Skin-friendly, allergy-free polypropylene</li> <li>Filter media: Polypropylene microfiber</li> <li>Ear loops: soft polyester and polyurethane, free from natural latex</li> <li>Nose piece: Plastic coated iron wire</li> </ul>			
Product Description:	Ergonomically formed face mask with easily adjustable nose piece. The outer layer and the inner layer consist of physiologically harmless soft nonwoven material.  With ear loops.			
Product performance:	Product performance according to EN 14683:2019+AC:2019			
	Testing	Performance class	Requirement	Test result
	Bacterial filtration efficiency (BFE), (%)	Type II	≥ 98	99,8
	Pressure difference (Pa/cm²)		< 60	25
	Microbiological cleanliness (CFU/g)		≤ 30	≤ 5,94
Dermatological compatibility:	No contraindications.			
Packaging and variants:	Packaging		Quantity	
	Dispenser box		50 pcs.	
	Shipping carton		2.000 pcs.	
GTIN:	202		4049825006107	



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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 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
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.

