


Product:	Model D Loop	
REF:	217	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	Class I accordingly Medical Device Regulation (EU) 2017/745 , annex VIII; UMDNS Code: 12-458.
Performance class:	Type IIR (fluid resistant), tested accordingly EN 14683:2019+AC:2019 for medical face masks.
Materials:	<ul style="list-style-type: none"> Outer layer: Polypropylene nonwoven Inner layer: skin friendly polypropylene nonwoven Filter medium: Polypropylene micro fiber Ear loops: soft polypropylene and elastane Nose clip: metal wire covered by HDPE
Product description:	<p>Medical face masks "Model D Loop" in film packaging containing 5 pieces. The "Model D" from DACH Schutzbekleidung is a type IIR medical face mask "Made in Germany".</p> <p>It exceeds normative requirements and reliably helps prevent nosocomial infections in hospitals by significantly reducing the spread of germs by the wearer.</p> <p>Low breathing resistance and soft ear loops make it comfortable to wear.</p> <p>The "Model D Loop" is available in classic blue and various other uplifting colours in a small 5-pack for on-the-go use.</p> <p>Latex-free, hypoallergenic, anatomically shaped face mask with easily moldable nosepiece.</p> <p>The inner and outer layers are physiologically safe and plasticizer-free. With ear loops - easy to put on and take off.</p>

Product performance:	<i>Product performance accordingly EN 14683:2019+AC:2019</i>			
	Test	Performance clas	Requirement	Test result
	Bacterial filtration efficiency (BFE), (%)	Typ IIR	≥ 98	>99
	Differential pressure(Pa/cm²)		< 60	25
	Splash resistance pressure (kPa)		≥ 16,0	16,0
	Microbial cleanliness (CFU/g)		≤ 30	≤ 12

	*CFU = colony forming units
Colours:	Blue, beige, orange, red, pink

Pakaging and Variants:	Packaging	Quantity	
	Bag	5 pcs.	
	Shipping Carton	350 pcs.	
GTIN:	217/B	Blue	4049825007067
	217/BG	Beige	4049825007074
	217/OR	Orange	4049825006992
	217/R	Red	4049825007050
	217/RO	Pink	4049825006978
Use:	<p>All materials used are free of irritants, odorless and suitable for medical purposes.</p> <p>Conform to the biological compatibility accordingly ISO 10993.</p> <p>The mask is worn by healthcare professionals in the patient environment to protect the patient.</p>		
Storage:	<p>Store dry in original packaging without direct sunlight (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 nature and extent of the contamination determines the disposal, following the applicable laws and regulations of the relevant country.</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> 