

# Product Data Sheet

<b>Product:</b>	Model D Loop	 
<b>REF:</b>	216-5	
<b>Manufacturer:</b>	DACH Schutzbekleidung GmbH & Co. KG	

<b>Classification:</b>	Class I accordingly Medical Device Regulation (EU) 2017/745 , annex VIII; UMDNS Code: 12-458.
<b>Performance class:</b>	Type IIR (fluid resistant), tested accordingly EN 14683:2019+AC:2019 for medical face masks.
<b>Materials:</b>	<ul style="list-style-type: none"> <li>Outer layer: Polypropylene nonwoven</li> <li>Inner layer: skin friendly polypropylene nonwoven</li> <li>Filter medium: Polypropylene micro fiber</li> <li>Ear loops: soft polypropylene and elastane</li> <li>Nose clip: metal wire covered by HDPE</li> </ul>
<b>Product description:</b>	<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>

<b>Product performance:</b>	<i>Product performance accordingly EN 14683:2019+AC:2019</i>			
	<b>Test</b>	<b>Performance class</b>	<b>Requirement</b>	<b>Test result</b>
	Bacterial filtration efficiency (BFE), (%)	Type IIR	≥ 98	>99
	Differential pressure(Pa/cm²)		< 60	25
	Splash resistance pressure (kPa)		≥ 16,0	16,0

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	Microbial cleanliness (CFU/g)	≤ 30	≤ 12
	*CFU = colony forming units		
<b>Colours:</b>	Blue, beige, orange, red, pink		

Pakaging and Variants:	Packaging	Quantity	
	Bag	5 pcs.	
	Shipping Carton	350 pcs.	
<b>GTIN:</b>	216-5/B	Blue	4049825007067
	216-5/BG	Beige	4049825007074
	216-5/OR	Orange	4049825006992
	216-5/R	Red	4049825007050
	216-5/RO	Pink	4049825006978
<b>Use:</b>	All materials used are free of irritants, odorless and suitable for medical purposes. Conform to the biological compatibility accordingly ISO 10993.		
<b>Storage:</b>	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 product).		
<b>Environmental sustainability and disposal:</b>	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. A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.		
<b>Indication:</b>	Non sterile. 		