

Product:	Neolution®Air Loop	 
REF:	257VP	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	
Classification:	▪ Category III Personal Protective Equipment (PPE) accordingly Regulation (EU) 2016/425. ▪ Class I Medical Device (MD) according to Regulation (EU) 2017/745. ▪ We recommend the use in clean rooms accordingly EN ISO 14644-1 (Helmke Drum Test accordingly IEST-PR-CC003.4, Category I): ISO class 3 to ISO class 9. ▪ EU GMP Annex 1, Class C and D.	
Protection class:	Particle filtering half mask FFP3 NR D with covered valve accordingly EN 149:2001+A1:2009. Additionally complies with the requirements for Type IIR medical face masks according to EN 14683:2019+AC:2019 in terms of bacterial filtration efficiency, splash resistance pressure and microbial cleanliness. Very good skin compatibility scientifically proven by testing accordingly EN ISO 10993-5 (cytotoxicity), EN ISO 10993-10 (sensitization) and EN ISO 10993-23 (irritation): The materials used are not cytotoxic, not sensitizing and not irritating.	
Materials:	▪ Mask: Polypropylene nonwoven ▪ Ear loops: textile elastic made from polyester and elastane ▪ Nose clip: metal wire covered by plastic ▪ Valve: Polypropylene ▪ Cover for valve: Composite material made of polypropylene spunbond and meltblown Mask is free from natural latex.	

Product description:	This mask is not only an excellent respirator with an exhalation valve that increases wearer comfort by preventing moisture and heat build-up. Thanks to the filtering valve cover, it retains germs and droplets from the wearer's breath and thus also protects the environment from contamination and potentially infectious aerosols. It is therefore ideal for cleanrooms and for use during surgical and medical procedures. The three-part respirator and medical face mask Neolution®Air Loop impresses with high-quality materials that guarantee the wearer maximum comfort. High-tech filter material generates a high filtering performance against solid and liquid aerosols with extremely low breathing resistance. Due to the three flexible mask parts, the mask follows the jaw movements when speaking. This ensures a constant tight fit. Quick and secure donning and doffing thanks to elastic ear loops. The thick ear loops fit comfortably around the ear without cutting in. Maximum protection even under extreme conditions: for disposable masks voluntary dolomite dust loading test passed!						
Product performance:	<i>Product performance accordingly EN 149:2001+A1:2009</i>						
	Filter efficiency						
	Class	Requirement			Test result		
		Maximum penetration			Actual penetration		
		NaCl 95 l/min	Paraffin oil 95 l/min		NaCl 95 l/min	Paraffin oil 95 l/min	
	FFP3 NR D	1%	1%	0,07 %	0,16 %		
	Breathing resistance						
	Class	Requirement			Test result		
		Maxium breathing resistance (mbar)			Actual breathing resistance (mbar)		
		Inhalation		Exhalation	Inhalation		Exhalation
30 l/min		95 l/min	160 l/min	30 l/min	95 l/min	160 l/min	
FFP3 NR D	1,0	3,0	3,0	0,4	1,7	2,5	
Leakage test							
Class	Requirement			Test result			

		Maximum total inward leakage (%)	Minimum Protection factor (Fit Factor)	Total inward leakage (%) ¹	Protection factor (Fit Factor) ^{1,2}
	FFP3 NR D	2	30	1,34	74,6
	¹ The leakage and protection factor values were determined as mean values with two test persons under laboratory conditions and are for reference only. The data does not represent the actual leakage of a person at the workplace and does not replace an individual fit test. ² The fit factor (protection factor) indicates the ratio between the particle concentration outside the mask and the particle concentration inside the mask.				
	Carbon dioxide content of inhalation air				
	Class	Requirement (max.)		Test result	
	FFP3 NR D	1%		0,56 %	

	Product performance according to EN 14683:2019 +AC:2019		
	Bacterial filtration efficiency (BFE)		
	Class	Requirement	Test result
	Type IIR	≥98 %	>99,9 %
	Splash resistance pressure		
	Class	Requirement	Test result
	Type IIR	≥16,0 kPa	16,0 kPa

	Microbial cleanliness		
	Class	Requirement	Test result
	Type IIR	Maximum CFU/g value	Actual CFU/g value
		< 30	≤ 16
	*CFU = colony forming units.		
	Test results Helmke-Drum Test IEST-PR-CC003.4 (Average)		

	Particle size		Particle count (per cm²)	Helmke-Drum Test IEST-PR-CC003.4 Climatic conditions: 18°C +/- 2°C, 50% - 10% RH
	≥ 0,3 µm - < 0,5 µm		0,00066	
	≥ 0,5 µm - <1,0 µm		0,00058	
	≥ 1,0 µm - < 5,0 µm		0,00058	
	≥ 5,0 µm		0,00006	
Packaging and Variants	Packaging	Quantity	GTIN	
	Box	20 pcs.	4049825007906	
	Carton	120 pcs.	4049825507895	
	EURO Pallet	6480 pcs.		
Colour:	White			
Use:	For single use. Read the instructions before use.			
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 labelling on the product).			
Environmental sustainability and disposal:	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.			