Product Data Sheet

Product:	Neolution®Air
REF:	256VP
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 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 compatibily 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 body: Polypropylene nonwoven ▪ Head straps: textile elastic made of polyester and elastane, free from natural latex ▪ Nose clip: metal wire covered with plastic ▪ Valve: Polypropylene ▪ Cover for valve: Composite material made of polypropylene spunbond and meltblown
Product Description:	The three-part respirator and medical face mask Neolution®Air 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 movable parts, the mask follows the jaw movements during speech. This ensures a constant tight fit. Textile head straps ensure a secure fit of the mask to the face. The straps fit comfortably on the head without pinching or pulling hair. Maximum protection even under extreme conditions: for disposable masks voluntary dolomite dust loading test passed!
Product performance:	*Product performance according to EN 149:2001+A1:2009*

Filter efficiency						
Class	Requirement			Test result		
	Maximum penetration			Actual penetration		
	NaCl 95 l/ min	Paraffin oil l95 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		
	Maximum 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	0,81		123,5
[1] The leakage and protection factor values were determined as mean values with 3 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 the inhaled 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	< 5
	*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.	4049825007913
	Shipping carton	120 pcs.	4049825507901
	Pallet	5760 Stk.	
GTIN:	256VP		
Colour:	White		
Use:	For single use. Read the instructions for use 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 labeling on the product).		

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.