DACH Schutzbekleidung
GmbH & Co. KG

Technical Data Sheet

NeolutionMed

Product description

The NeolutionMed respirator has been developed for the use in medical environments and provides reliable protection against airborne infectious agents, aerosols and non-volatile liquid particles.

Equipped with high-performing material, the NeolutionMed combines highest filter performance with low breathing resistance, ensuring maximum safety for the medical staff and the patient. The extra-large filter surface can absorb large amounts of particles and provides a large mask volume for maximum comfort even after prolonged wearing.

The three-part foldable design ensures a secure fit for all face shapes and is also easy to handle and space saving when stored.

The intelligent NeolutionMed design offers maximal freedom of movement and flexibly adapts while speaking or during other physical activity. So that it stays securely fitted and prevents dangerous slipping, providing reliable protection at the workplace.

The wide chin flap seals the chin area and facilitates easy positioning of the mask.

The nose piece can be adjusted to fit every individual nose shape and its metal material makes the mask detectable.

Classification

Category III in accordance with the Regulation (EU) 2016/425 on personal protective equipment (PPE).

EU Type examination and surveillance through BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Niederlande, CE2797.

Standards

Tested accordingly EN 149:2001+A1:2009, the NeolutionMed is a FFP3 NR respirator. Additionally tested accordingly EN 14683:2019 for Type II R surgical masks.

Requirements of the standard EN 14683: 2019 for Type II R

The Bacterial Filter Efficiency (BFE) meets the following requirements:

Type	Bacterial Filtration Efficiency (BFE)
Type II R	≥ 98 %

The resistance against synthetic blood penetration meets the following requirements:

Type	Test pressure
Type II R	≥ 16,0 kPA (≙ 120mmHg)

The Microbial Cleanliness (Bioburden) meets the following requirements:

Type	Microbial Cleanliness
Type II R	≤ 30 CFU/g *

*CFU = colony forming units

Requirements of the standard EN 149:2001+A1:2009

The total inward leakage meets the following requirements.

Class	Total inward leakage
FFP3	2 %

The filter penetration meets the following requirements.

Class	Maximum penetration	
	NaCl 95 l/min	Paraffin oil 95 l/min
FFP3	1 %	1 %

The breathing resistance meets the following requirements.

Class	Maximum permissible breathing resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP3	1,0	3,0	3,0

Inflammability meets the requirements of EN 149: 2001 + A1: 2009: All materials pose no danger to the user and are not readily flammable.

Application

NeolutionMed protects the wearer against solid and fluid aerosols up to 30 times the Occupational Exposure Limit (OEL) value.

National regulations must be followed.

Material

Exterior & Interior:	Polypropylene nonwoven
Supporting layer:	Polyester nonwoven
Filter medium:	Polypropylene
Nose piece:	Iron wire covered by polyethylene, detectable
Nose pad foam:	Polyethylene foam
Elastic band:	Latex-free synthetic rubber

All materials used are free from irritant substances.

Packaging

REF	GTIN	Packed	Quantity
233	4049825004073	Box	40
		Carton	480

Requirements for use

National regulations must be followed, eg. DGUV Rule 112-190 (BGR 190) "Use of respiratory protective equipment", BGI 504-26 "Selection criteria for special occupational medical precaution according to the professional association principle", G26 "Respiratory protective devices".

The instructions for use must be read and followed. The user must be familiar with the use and handling of the device.

The oxygen content of the breathing air must be at least 17 vol%. (DACH recommends 19 vol%)

Unventilated containers, pits, channels and small spaces must not be entered with particle filtering half masks.

The type and concentration of hazardous substances must be known.

Particle filtering half masks do not protect against gases.

The respirator is not suitable for users with heavy facial hair or deep scars around the sealing lines of the mask.

Wearing time

One working shift. For hygienic reasons, the respirator for medical use must be disposed of after use.

Storage

Store in a dry environment, no of direct sunlight in its original packaging, see also packaging. The product has a shelf life of 3 years if the recommended storage conditions are followed.

Disposal

This product can be thermally recycled or disposed in a controlled landfill without releasing toxic substances.

The disposal of contaminated products must be determined by its contamination. Please follow the respective laws and regulations.