5 LAYER PROTECTIONANTI-PARTICLE PROTECTIVE





Technical Specifications

Description

Mehma FFP2/N95 face mask provides effective respiratory protection in various environments for example medical, industrial etc where workers will be exposed to non-volatile solid and/or liquid particles (dusts, mists, fumes, virus particles etc).

- Contains 5 layers of filtration to block smallest of the particles.
- Flat fold shape.
- Ear loop made by two elastic straps.
- Adjustable nose-clip between the filter material layers and soft inner lining on nose, to ensure a good face seal over a range of face sizes.
- NR marking to specify that the facepieces is a single use item and it is Not Reusable for more than one work shift.
- Tested and CE approved to new EN 149:2001+A1:2009 standard.
- The individual packaging of the facepiece offers greater hygiene and maintenance and avoids any contamination.
- Manufactured using Good Manufacturing Practices (GMP).

Materials

- The following materials are used in the production of Mehma FFP2/N95 face mask: Filter: filtering material in 2 layers, non-irritating, polypropylene non-woven fabric
- Nose clip: reinforced plastic material
- Spunbound and cotton fabric which is comfortable on the face.
- Elastic straps which are comfortable on the ear.

EN 149:2001+A1 Test		Requirements FFP2	Mehma FFP2
Total filtering efficiency %		>95	97
Breathing resistance mbar	inhale. 30 l/min	<0.7	0.4
	inhale. 95 l/min	<2.4	1.4
	exhale. 160 l/min	<3.0	1.5
Filter material efficiency (%)	after 3 min	>94	97
	after 63 min (exposure test)	>94	98









Level of protection

Mehma FFP2/N95 face mask is suitable for protection against non-volatile solid and/or liquid particles, providing protection at a rate of more than 95%.

Cleaning

Mehma FFP2/N95 face mask is NR marked, i.e. it is not reusable and should not be washed.

Storage and transportation

Mehma FFP2/N95 face mask has a shelf life of 5 years. End of shelf life (expiry date) is marked on the product packaging. Product should be stored in clean, dry conditions within the temperature range: +5°C to +40°C with a maximum relative humidity of 60%. When storing or transporting this product, use original packaging provided.

Certification

Mehma FFP2/N95 face mask meets the requirements of the European Directive 89/686/EEC (Personal Protective Equipment) and is thus CE marked, as a PPE of III category, according to EN 149:2001+A1:2009 standard. CE Certification (Art.10) and control (Art.11.B) have been issued by BSI (British Standard Institute).

Mehma Medical has been independently assessed and accredited to the BS EN ISO 13485:2016 Medical Devices Quality Management Systems and BS EN ISO 9001:2015 Quality Management Systems, standards and guidelines.







Certification Tests

Practical performance

The particle filtering half mask undergoes practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in the specific standard. During the tests the particle filtering half mask is subjectively assessed for the following:

- head harness comfort;
- security of fastenings;
- field of vision;

Total inward leakage

The tests indicate that the particle filtering half mask can be used to protect with high probability against the potential hazard to be expected. The total inward leakage consists of two components: face seal leakage and filter penetration.

Breathing resistance

The breathing resistance offered by the filter has been tested with 30 l/min and 95 l/min airflows for the inhalation and 160 l/min airflow for the exhalation.

Warnings

- This product does not protect the operator against gases and vapours.
- Not to be used in atmospheres containing less than 17% oxygen.
- Do not use when the concentrations of the contaminants are immediately dangerous for life or health.
- Do not alter or modify the product in any way.
- Discard and replace the mask if it becomes damaged or if breathing becomes difficult.
- Store the face masks in a dry and clean room at a temperature within +5 °C and + 40 °C and relative humidity < 60%. If stored correctly and in the original packaging the product has a shelf life of 5 years.



