Medicom
Kolmi® Oxygen

Technical Data Sheet

M51014S-WH-MB

Respiratory protective mask FFP1 NR D - Type IIR - Mass Balance

Personal Protective Equipment Cat.III - Medical Device Class I

FEATURES AND BENEFITS

- Filtering half mask, efficiency class FFP1 NR D developed to protect against solid and liquid aerosols and particles.
- Type IIR certified, it protects the environment against droplets emitted by the wearer and it protects him from potential body fluids splashes.
- Knitted headloops ultrasonically welded for an optimal comfort.
- Thanks to its shape, and the use of soft materials, the mask fits perfectly to the face to limit inward leakage.
- This mask is hypoallergenic and has been dermatologically tested*.
- Made in France.

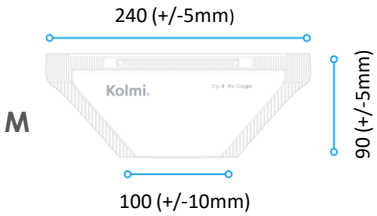
*Tested on a panel of 32 people by an accredited laboratory

Recommended use

- Use in dusty environment
- To prevent against risky infectious diseases
- Intended to be worn by patients and others to reduce the risk of spreading infection, especially in epidemic or pandemic situations.

PRODUCT DETAILS

Product name :	**Kolmi Oxygen**
Product type :	Single use, non sterile
Fasteners :	Headloops
Nose piece :	Polypropylene and metal
Color :	White
Quantity / box :	50 units
Unit wieght :	8 g
Origin :	France



The Mass Balance approach: made up of 70% recycled material, our FFP Mass Balance range reduces the consumption of polypropylene from fossil resources. This chain of custody allows the recycled material added at the beginning of the production process of the mask components to be attributed to the finished product. This approach, which uses a chemical recycling process using heat, allows used polypropylene to be returned to the monomer state and thus retain the same characteristics as virgin polypropylene. Therefore, the performances of our Mass Balance FFP range are strictly similar to our standard range

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Personal Protective Equipment Cat.III - Medical Device Class I

CERTIFICATIONS & STANDARDS

- In accordance with requirements of Reg (EU) 2017/745 on medical devices.
- In accordance with requirements of Reg (EU) 2016/425 on personal protective equipment.
- In accordance with requirements of the Swiss Ordonnance on medical device (ODim) from July 1st 2020.
- Comply with the applicable standards EN 14683:2019 and EN 149:2001+A1:2009.
- Manufacturing site: ISO 9001 and ISO 13485 certification

MICROBIOLOGICAL INFORMATION

- Assessment of initial microbial contamination according to standards EN 14683: 2019+AC:2019 & ISO 11737: 2018+A1:2021.
- Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

EN 149:2001+A1:2009

TEST	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	RESULTS
Oil paraffin penetration	< 20 % after 120mg exposure	Apave (0082)	N° 24.0483 12/06/2024	Compliant
NaCl penetration	< 20 % after 120mg exposure			Compliant
Total inward leakage	≤ 25 % for at least 46 results over 50 ≤ 22 % for at least 8 arithmetic average over 10			Compliant
Air permeability inhalation 30 l/min	≤ 0,6 mbar			Compliant
Air permeability inhalation 95 l/min	≤ 2,1 mbar			Compliant
Air permeability exhalation 160 l/min	≤ 3 mbar			Compliant
Carbon dioxide content	< 1,0 %			Compliant
Flammability	Must not burn or continue to burn for more than 5 seconds after the withdrawal of the flame			Compliant
Protection (D) : protection against solid and liquid aerosols, combined with resistance higher to clogging tested with dolomite dust				
Annual surveillance according to module D - Reg (EU) 2016/425 done by APAVE (0082)				

EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT n° & DATE	RESULTS
Bacterial Filtration Efficiency: BFE	EN 14683:2019	≥ 98% (Type IIR)	Nelson	1362446-S01 08/12/2020	99,9%
DELTA P	EN 14683:2019	< 60 Pa/cm²	Nelson	1362448-S01 30/11/2020	55,78 Pa/cm² max
SPLASH	ISO 22609:2004	≥ 16 kPa	Centexbel	20.07751.03 07/01/2021	Compliant
Cytotoxicity	ISO 10993-5	no cytotoxicity	Namsa	287995 14/01/2021	No cytotoxicity
Irritation	ISO 10993-10	no irritation	Namsa	20T_77155_04&05 08/03/2021	No irritation
Sensitization	ISO 10993-10	no sensitization	Namsa	287999 22/02/2021	No sensitization

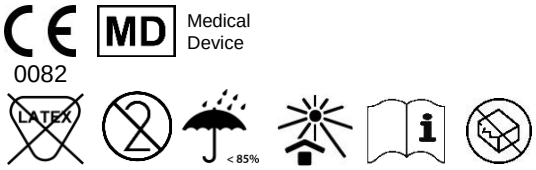
PRECAUTIONS OF USE

The device should only be used on intact skin only.
Their reuse or prolonged use may result in infection or cross-contamination.
After use, comply with the current national regulations for disposing of the device.

STORAGE CONDITIONS

Normal storage conditions: should not be exposed to moisture and sunlight, must be stored at room temperature.
Product shelf life: 5 years.

PACKAGING MARKING



LOGISTICS

Outer case spec.

Item	Size mm	Gross weight (kg)	Qty/ pallet
M51014S-WH-MB	580 x 275 x 300	5,05	36

Inner box spec.

Size mm	Gross weight (g)	Packaging
255 x 110 x 133	475	10 x 50 units

EAN codes

Item	Inner box	Outer case
M51014S-WH-MB	3 662 036 022 677	3 662 036 022 660

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