Medicom
Kolmi® Oxygen

Technical Data Sheet

M53014(S)-WH-MB
M53114(S)-WH-MB
M53214(S)-WH-MB

Respiratory protective mask FFP3 NR D - Type IIR - Mass Balance

Personal Protective Equipment Cat.III - Medical Device Class I

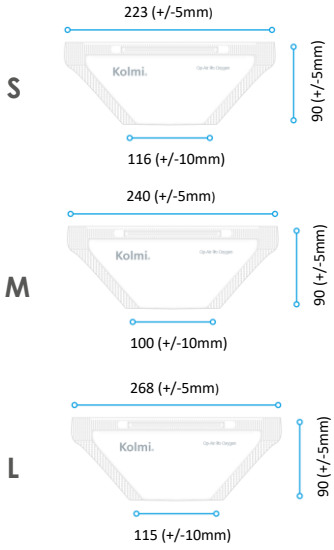
FEATURES AND BENEFITS

- Filtering half mask, efficiency class FFP3 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
Origin :	France

MEDICOM USES RECYCLED PLASTIC

The Mass Balance approach: made up to **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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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.
- Meets applicable requirements of EN 14683:2025* 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 14683:2025* & 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	< 1 % after 120mg exposure	Apave (0082)	N° 24.0468 03/06/2024	Compliant
NaCl penetration	< 1 % after 120mg exposure			Compliant
Total inward leakage	≤ 5 % for at least 46 results over 50 ≤ 2 % for at least 8 arithmetic average over 10			Compliant
Air permeability inhalation 30 l/min	≤ 1 mbar			Compliant
Air permeability inhalation 95 l/min	≤ 3 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 14683:2025*					
TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT n° & DATE	RESULTS
Bacterial Filtration Efficiency: BFE	EN 14683:2025*	≥ 98% (Type IIR)	Nelson	1362441-S01 14/12/2020	99,9%
SPLASH	ISO 22609:2004	≥ 16 kPa	Centexbel	20.07751.02 07/01/2021	Compliant
Cytotoxicity	ISO 10993-5	no cytotoxicity	Namsa	290637 11/03/2021	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

*based on testing to EN14683:2019 + AC:2019

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. / Inner box spec.

Item	Mask size	Size (mm)	Gross weight (kg)	QTY/ pallet	Size (mm)	Gross weight (g)	Packaging
M53014S-WH-MB	M	560 x 260 x 270	4,2	36	255 x 110 x 133	400	10 x 50
M53014-WH-MB	M	560 x 260 x 270		36	255 x 110 x 133		10 x 50
M53214-WH-MB	S	560 x 260 x 270	3,9	36	255 x 110 x 133		10 x 50
M53214S-WH-MB	S	560 x 260 x 270		36	255 x 110 x 133		10 x 50
M53114S-WH-MB	L	355 x 235 x 330	3,6	45	300 x 110 x 133		4 x 50
M53114-WH-MB	L	355 x 235 x 330		45	300 x 110 x 133		4 x 50

S = mask individually packed

EAN Codes

Item	Outer case	Inner box
M53014S-WH-MB	3 662 036 020 666	3 662 036 020 673
M53014-WH-MB	3 662 036 020 642	3 662 036 020 659
M53214-WH-MB	3 662 036 020 604	3 662 036 020 611
M53214S-WH-MB	3 662 036 020 628	3 662 036 020 635
M53114-WH-MB	3 662 036 020 680	3 662 036 020 697
M53114S-WH-MB	3 662 036 020 703	3 662 036 020 710

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