Medicom

Kolmi® Oxygen

# Technical Data Sheet

**M52014(S)-WH-MB**
**M52114(S)-WH-MB**
**M52214(S)-WH-MB**

## Respiratory protective mask FFP2 NR D - Type IIR - Mass Balance

**Personal Protective Equipment Cat.III - Medical Device Class I**



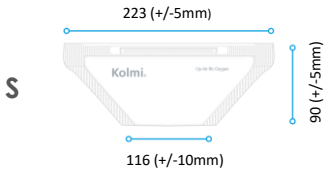
## FEATURES AND BENEFITS

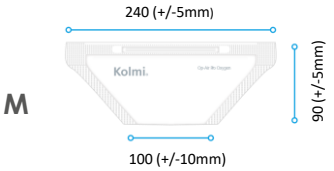
- Filtering half mask, efficiency class FFP2 NR D developed to protect against solid and liquid aerosols and particles.
- Type IIR certified, it protects the environment against droplets emitted by the wearer, and it protects him from potential body fluids splashes.
- Knitted headloops ultrasonically 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.

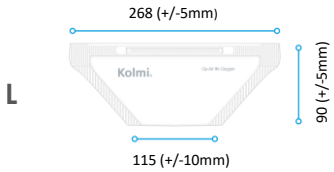
*Tested on a panel of 32 people by an accredited laboratory

### 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 |

**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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# M52014(S)-WH-MB
# M52114(S)-WH-MB
# M52214(S)-WH-MB

## Respiratory protective mask FFP2 NR D - Type IIR - Mass Balance

**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.
- Meets applicable requirements of EN 14683:2025 *based on testing to EN14683:2019 + AC: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.

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| EN 149:2001+A1:2009 | | | | |
|---|---|---|---|---|
| TEST | REQUIRED LEVEL | LABORATORY | REPORT N° & DATE | RESULTS |
| Oil paraffin penetration | < 6 % after 120mg exposure | Apave (0082) | N° 24.0559 20/06/2024 | Compliant |
| NaCl penetration | < 6 % after 120mg exposure | | | Compliant |
| Total inward leakage | ≤ 11 % for at least 46 results over 50<br>≤ 8 % for at least 8 arithmetic average over 10 | | | Compliant |
| Air permeability inhalation 30 l/min | ≤ 0,7 mbar | | N°24.0467 03/06/2024 | Compliant |
| Air permeability inhalation 95 l/min | ≤ 2,4 mbar | | N°24.0562 20/06/2024 | 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 14683:2019 | ≥ 98% (Type IIR) | Nelson | 1362446-S01 08/12/2020 | 99,9% |
| 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 | Mask size | Size (mm) | Gross weight (kg) | QTY/ pallet |
|---|---|---|---|---|
| **M52014S-WH-MB** | M | 560 x 260 x 270 | 4 | 36 |
| **M52014-WH-MB** | M | 560 x 260 x 270 | 4 | 36 |
| **M52214S-WH-MB** | S | 560 x 260 x 270 | 3,6 | 36 |
| **M52214-WH-MB** | S | 560 x 260 x 270 | 3,6 | 36 |
| **M52114S-WH-MB** | L | 355 x 235 x 330 | 2 | 45 |
| **M52114-WH-MB** | L | 355 x 235 x 330 | 2 | 45 |

### Inner box spec.

| Size (mm) | Gross weight (g) | Packaging |
|---|---|---|
| 255 x 110 x 133 | 380 | 10 x 50 u. Indiv. wrapped |
| 255 x 110 x 133 | 380 | 10 x 50 u. |
| 255 x 110 x 133 | 340 | 10 x 50 u. Indiv. wrapped |
| 255 x 110 x 133 | 340 | 10 x 50 U. |
| 300 x 110 x 133 | 450 | 4 x 50 u. Indiv. wrapped |
| 300 x 110 x 133 | 450 | 4 x 50 u. |

### EAN codes

| Item | Outer case | Inner box |
|---|---|---|
| **M52014S-WH-MB** | 3 662 036 020 543 | 3 662 036 020 550 |
| **M52014-WH-MB** | 3 662 036 020 529 | 3 662 036 020 536 |
| **M52214S-WH-MB** | 3 662 036 020 505 | 3 662 036 020 512 |
| **M52214-WH-MB** | 3 662 036 020 482 | 3 662 036 020 499 |
| **M52114-WH-MB** | 3 662 036 020 567 | 3 662 036 020 574 |
| **M52114S-WH-MB** | 3 662 036 020 598 | 3 662 036 020 581 |

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