Technical Data Sheet

OP-air® PRO oxygen

Respiratory protective mask

FFP3 NR D & Type IIR - Mass Balance

Personal Protective Equipment Cat III
EN 149:2001 + A1:2009 – FFP3 NR D
Medical device, Class I
EN14683:2019+AC:2019 - Type IIR

KOLMI HOPEN · USES RECYCLED PLASTIC ·

The Mass Balance approach: made up of **70% recycled material**, the OP-air PRO Oxygen 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 OP-air PRO Oxygen Mass Balance range are **strictly similar to our standard range**

FEATURES & BENEFITS

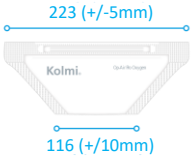
- Filtering half mask, efficiency class FFP3 NR D developed to protect against solid and liquid aerosols and particles.
- Type IIR certified, it protects the environment against droplets emitted by the wearer and it protects him from potential body fluids splashes.
- Knitted headloops ultrasonically welded for an optimal comfort.
- Thanks to its shape, and the use of soft materials, the OP-air® Pro Oxygen fits perfectly to the face to limit inward leakage.
- This mask is hypoallergenic.
- OP-air® Pro Oxygen is made in France.

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.

SIZES & DIMENSIONS

M53214-WH-MB **S**



M53014S-WH-MB*
M53014-WH-MB **M**

M53114S-WH-MB* **L**

*Individually packed

PRODUCT DETAILS

Product Name:	OP-air® Pro Oxygen
Product Type:	Single-use, non-sterile
Fasteners:	Headloops
Nosepiece:	Polypropylene and metal
Colour:	White
Quantity per box:	50
Country of Origin:	FRANCE

CERTIFICATIONS & STANDARDS

In accordance with requirements of Reg (EU) 2017/745 and UK Medical Device Regulation 2002, on medical devices.
In accordance with requirements of Reg (EU) 2016/425 on personal protective equipment and Regulation 2016/425 on personal protective equipment, as amended to apply in Great Britain.
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**	**AVERAGE RESULT**
Oil paraffin penetration	< 1 % after 120mg exposure	Apave (0082)	N° 22.0395 27/07/2022	0,30%
NaCl penetration	< 1 % after 120mg exposure			0,16%
Total inward leakage	≤ 5 % for at least 46 results over 50 ≤ 2 % for at least 8 arithmetic average over 10			≤ 5 % for 50 results over 50 ≤ 2 % for 8 arithmetic average over 10
Air permeability inhalation 30 l/min	≤ 1 mbar			0,24 mbar
Air permeability inhalation 95 l/min	≤ 3 mbar			0,87 mbar
Air permeability exhalation 160 l/min	≤ 3 mbar			1,19 mbar
Carbon dioxide content	< 1,0 %			0,74%
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 (UE) 2016/425 done by APAVE (0082)				

EN 14683:2019+AC:2019					
TEST	**NORME**	**NIVEAU EXIGÉ**	**LABORATOIRE**	**N°RAPPORT & DATE**	**RÉSULTATS**
Bacterial Filtration Efficiency: BFE	EN 14683:2019	≥ 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

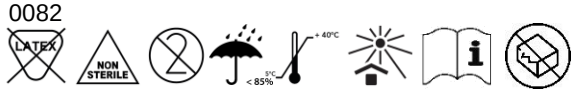
Always ensure the product is:

- Suitable for use
- Used on clean, healthy skin only
- Fitted correctly
- Worn during all period of exposure
- Not re-used

Please refer to your national legislation on the subject of disposal of this products once it has been used.

PACKAGING MARKING

CE 0082 UKCA MD Medical Device



STORAGE CONDITIONS

Normal storage conditions: should not be exposed to moisture and sunlight, should be stored in a cool environment or at room temperature.
Shelf life: 5 years.

LOGISTICS

INNER CASE SPEC.				OUTER CASE SPEC.		
ITEM	**QTY**	**SIZE (MM)**	**BOX BARCODE**	**QTY/PALLET**	**SIZE (MM)**	**OUTER CASE BARCODE**
M53214-WH-MB	10 boxes of 50 units	255 x 110 x 133	3 662 036 020 611	36	560 x 260 x 270	3 662 036 020 604
M53014-WH-MB	10 boxes of 50 units	255 x 110 x 133	3 662 036 020 659	36	560 x 260 x 270	3 662 036 020 642
M53014S-WH-MB	10 boxes of 50 units Individually packed	255 x 110 x 133	3 662 036 020 673	36	560 x 260 x 270	3 662 036 020 666
M53114S-WH-MB	4 boxes of 50 units Individually packed	300 x 110 x 133	3 662 036 020 710	45	355 x 235 x 330	3 662 036 020 703