

TECHNICAL DATA SHEET

OP-air® PRO oxygen

Respiratory protective mask FFP 3 NR D Type IIR

Personal Protective Equipment Cat III
EN 149:2001 + A1:2009

Medical device, class I
EN14683:2019+AC:2019 Type IIR



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.
- 3 sizes available
- OP-air® Pro Oxygen is made in France

RECOMMENDED USE

- Use in dusty environment
- To prevent against risky infectious diseases

PRODUCT DETAILS

Product Name: OP-air® Pro Oxygen
Product Type: Single-use, non-sterile
Interior Layer: Spunbonded polypropylene
Filter: Meltblown polypropylene
Exterior Layer: Spunbonded polypropylene
Strap: Headloops
Nosepiece: Polypropylene and metal
Colour: White
Quantity per box: 50
Country of Origin: FRANCE

ITEM	SIZE	DIMENSIONS
M53214-WH	S	 240 (+/- 5mm) 113 (+/- 5mm) 90 (+/- 5mm)
M53014S-WH* M53014-WH	M	 225 (+/- 5mm) 113 (+/- 5mm) 90 (+/- 5mm)
M53114S-WH*	L	 270 (+/- 5mm) 113 (+/- 5mm) 90 (+/- 5mm)

*Individually packed

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2016/425 on personal protective equipment.

Comply with the applicable standards EN 14683:2019 and EN 149:2001+A1:2009.

Manufacturing site: ISO 9001 and ISO 13485 certification

EN 149:2001+A1:2009

TEST	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULT
Oil paraffin penetration	< 1 % after 120mg exposure	INSPEC 2849	1.20.08.39 21/08/2020	Compliant
NaCl penetration	< 1 % after 120mg exposure			Compliant
Facial 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 mbars			Compliant
Air permeability inhalation 95 l/min	≤ 3 mbars			Compliant
Air permeability exhalation 160 l/min	≤ 3 mbars			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 observation according to module C2 - Reg (UE) 2016/425 done by INSPEC (2849)				

EN 14683:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	RESULTS
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 08/03/2021	no irritation
Sensitization	ISO 10993-10	no sensitization	Namsa	287999 22/02/2021	no sensitization

MICROBIOLOGICAL INFORMATION

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

PRECAUTIONS

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.



STORAGE CONDITIONS

Product should be stored in clean, dry condition with in the temperature range 5°C and 40°C.
Shelf life of the product: 5 years

LOGISTICAL INFORMATION

INNER CASE SPECIFICATIONS				OUTER CASE SPECIFICATIONS		
ITEM	QTY	SIZE (MM)	BOX BARCODE	QTY/PALLET	SIZE (MM)	OUTER CASE BARCODE
M53214-WH	10 boxes of 50 units	255 x 110 x 133	3 662 036 018 410	36	560 x 260 x 270	3 662 036 018 427
M53014S-WH	10 boxes of 50 units Individually packed	255 x 110 x 133	3 662 036 018 397	36	560 x 260 x 270	3 662 036 018 403
M53014-WH	10 boxes of 50 units	255 x 110 x 133	3 662 036 018 380	36	560 x 260 x 270	3 662 036 018 380
M53114S-WH	4 boxes of 50 units	300 x 110 x 133	3 662 036 018 489	45	355 x 235 x 330	3 662 036 018 472