

TECHNICAL DATA SHEET

OP-air® PRO oxygen

Respiratory protective mask

FFP2 NR D Type IIR

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

Medical device, class 1
EN14683:2019+AC:2019 Type IIR



FEATURES & 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 OP-air® Pro Oxygen fits perfectly to the face to limit inward leakage.
- This mask is hypoallergenic and has been dermatologically tested*.
- 3 sizes available
- OP-air® Pro Oxygen is made in France

RECOMMENDED USE

- Use in dusty environment
- To prevent against risky infectious diseases
- FFP masks can also be worn by patients and other people to reduce the risk of spreading infection, particularly in epidemic or pandemic situations.

PRODUCT DETAILS

Product name :	OP-air® Pro Oxygen
Product type :	Single-use, non-sterile
Inner layer :	Spunbonded polypropylene
Filter:	Meltblown polypropylene
Outer layer :	Spunbonded polypropylene
Fasteners :	Headloops
Nose piece:	Polypropylene & metal
Color :	White
Qty per box :	50
Manufacturing country:	FRANCE

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 harmonized standards EN 14683:2019+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.

Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

ITEM	SIZE	DIMENSIONS
M52214-WH M52214S-WH*	S	
M52014S-WH* M52014-WH	M	
M52114S-WH* M52114-WH	L	

* Individually packed

*Tested on a panel of 32 people by an approved laboratory.

EN 149:2001+A1:2009

TEST	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	RESULTS
Oil paraffin penetration	< 6 % after 120mg exposure	APAVE	20.0380 21/09/2020	Compliant
NaCl penetration	< 6 % after 120mg exposure			Compliant
Facial leakage	≤ 11 % for at least 46 results over 50 ≤ 8% for at least 8 arithmetic average over 10			Compliant
Air permeability inhalation 30 l/min	≤ 0,7 mbars			Compliant
Air permeability inhalation 95 l/min	≤ 2,4 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 D - Reg (UE) 2016/425 done by APAVE

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	57,1 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
Intracutaneous irritation test	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

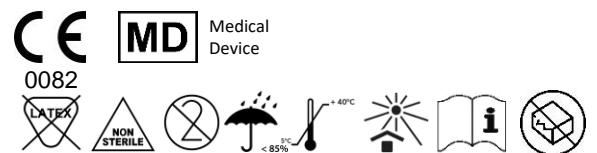
PRECAUTIONS

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.

PACKAGING MARKING



STORAGE CONDITIONS

Normal storage conditions: should not be exposed to moisture and sunlight, should be stored at a temperature between 5°C and 40°C.

Shelf life of the product: 5 years.

LOGISTICS INFORMATION

INNER CASE SPECIFICATIONS				OUTER CASE SPECIFICATIONS		
ITEM	QTY	SIZE (mm)	BOX BARCODE	QTY/PALLET	SIZE (mm)	OUTER CASE BARCODE
M52014-WH	10 boxes of 50 units	255 x 110 x 133	3 662 036 018 182	36	560 x 260 x 270	3 662 036 018 175
M52014S-WH	10 boxes of 50 units Individually packed	255 x 110 x 133	3 662 036 018 229	36	560 x 260 x 270	3 662 036 018 212
M52214S-WH	10 boxes of 50 units Individually packed	255 x 110 x 133	3 662 036 020 390	36	560 x 260 x 270	3 662 036 020 383
M52214-WH	10 boxes of 50 units	255 x 110 x 133	3 662 036 020 376	36	560 x 260 x 270	3 662 036 020 369
M52114S-WH	4 boxes of 50 units Individually packed	300 x 110 x 133	3 662 036 020 413	45	355 x 235 x 330	3 662 036 020 406
M52114-WH	4 boxes of 50 units	300 x 110 x 133	3 662 036 020 420	45	355 x 235 x 330	3 662 036 020 437