

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

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.

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 21.0819 & 21.0644 17/12/2021	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

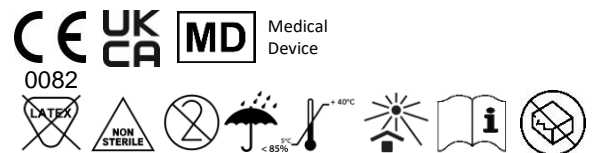
PRECAUTIONS

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