



SAFE+OXYGEN

2292-WH RESPIRATORY PROTECTION MASK – Small

Personal Protective Equipment, Category III and Medical Device, Class I

FEATURES & BENEFITS

- Filtering half mask, efficiency class FFP2 NR D developed to protect
- against solid and liquid aerosols
- Ultrasonic welding

Recommended use:

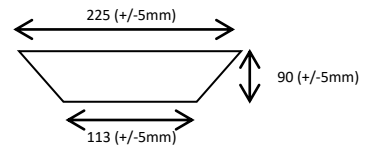
- Use in dusty environment
- To prevent against risky infectious diseases (According to national recommendations)
- Using time: 8 H



Item	2292-WH
Colour	White
	<input type="checkbox"/>

PRODUCT DETAILS

Product name:	Mask FFP2 NR D – Small size
Product type:	Single use, non-sterile
Outer/Inner layer:	Spunbond polypropylene
Filter:	Meltblown polypropylene
Link:	Headloops
Nosepiece:	Polypropylene and iron
Colour:	Blue / White
Unit weight:	5,8 g (± 10%)
Origin:	France



EN 149:2001+A1:2009

Test	Required level	Laboratory	Report number	Date of Report	Average value
Paraffin Oil penetration	< 6 % after 120mg exposure	APAVE	19.0029	22/01/2019	Conforme
NaCl penetration	< 6 % after 120mg exposure				Conforme
Facial leakage	46 results ≤ 11 % 8 averages in 10 ≤ 8%				Conforme
Air permeability inhalation 30 l/min	≤ 0,7 mbars				Conforme
Air permeability inhalation 95 l/min	≤ 2,4 mbars				Conforme
Air permeability exhalation 160 l/min	≤ 3 mbars				Conforme
Carbon dioxide content	< 1,0 %				Conforme
Flammability	Must not burn or continue to burn for more than 5 seconds after the withdrawal of the flame				Conforme

Protection (D) : protection against solid and liquid aerosols, combined with resistance higher to clogging tested with dolomite dust

*Average of the test results (Receiving State + Simulated port processing)

Annual observation according to module D - Reg (UE) 2016/425 done by APAVE

SAFE+OXYGEN 2292-WH RESPIRATORY PROTECTION MASK – Small Personal Protective Equipment, Category III and Medical Device, Class I

EN 14683:2019

Test	Standard	Required level	Laboratory	Report number	Date of Report	Value
Bacterial Filtration Efficiency: BFE	EN 14683:2019	> 98% (Type IIR)	CENTEXBEL	20.00718.02	20/03/2020	99.9% min
DELTA P	EN 14683:2019	< 60 Pa/cm ²	CENTEXBEL	20.00718.02	20/03/2020	46,3 Pa/cm ² max
SPLASH	ISO 22609:2004	≥ 16 kPa	CENTEXBEL	20.00718.02	20/03/2020	Compliant
Intracutaneous irritation test	ISO 10993-10	no irritation	NAMSA	231037	21/06/2017	no irritation
Cytotoxicity	ISO 10993-5	no cytotoxicity	NELSON	1030830-S01	20/03/2018	no cytotoxicity
Sensitization	ISO 10993-10	no sensitization	NAMSA	231038	19/06/2017	no sensitization
Microbial cleanliness	NF 11737:2018	≤30 CFU/g	MICROSEPT	1812011-15	14/04/2020	Compliant

CERTIFICATION & STANDARDS

Manufactured under ISO 9001 & EN ISO 13485 certified quality system.

In accordance with requirements of Personal Protective Equipment Reg. (EU) 2016/425 and with EN 149:2001+A1:2009

Complies with the requirements of Regulation (EU) 2017/745 relating to Medical Devices and with EN 14683:2019

PRECAUTIONS

The device should only be used on clean, healthy skin.

Their re-use or prolonged use can produce infection or cross-contamination.

After use, comply with the national regulations in force for the disposal of the device.

STORAGE CONDITIONS

Normal conditions of conservation & storage: not to be exposed to moisture and sun, must be stored at a temperature between 5°C and 40°C

Shelf life of the product: 5 years



LOGISTICAL INFORMATION



Outer case specifications

Inner case specifications

Item	Size mm	Gross weight kg	QTY/pallet	Size mm	Packaging	QTY
2292-WH	560 x 260 x 270	3,6	36 cartons (6 layers of 6 cartons)	255 x 110 x 133	Bulk	10 boxes of 50 pieces