



SAFE+OXYGEN

2192S-WH EN 149:2001+A1:2009 FFP2 NR D – EN 14683:2019 Type IIR

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:

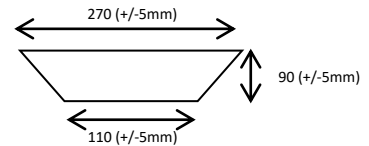
- Use in dusty environment
- To prevent against risky infectious diseases (According to national recommendations)
- Using time: 8 H



Item	2192S-WH
Colour	White
	<input type="checkbox"/>

PRODUCT DETAILS

Product name:	Mask FFP2 NR D – Large size
Product type:	Single use, non-sterile
Outer/Inner layer:	Spunbond polypropylene
Filter:	Meltblown polypropylene
Link:	Synthetic elastic
Nosepiece:	Polypropylene and iron
Colour:	Blue / White
Unit weight:	6,5 g (± 10%)
Origin:	France



EN 149:2001+A1:2009

Test	Required level	Laboratory	Report number	Date of Report	Results
Paraffin Oil penetration	< 6 % after 120mg exposure	APAVE	19.0029	22/01/2019	Compliant
NaCl penetration	< 6 % after 120mg exposure				Compliant
Facial leakage	46 results ≤ 11 % 8 averages in 10 ≤ 8%				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

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

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

NF 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
Using time : BFE + Delta P	EN 14683:2014	> 98% (Type IIR) < 49 Pa/cm ²	NELSON	961620-S01	10/05/2017	8h : > 99.9% 8h : 37,17 Pa/cm ²

CERTIFICATION & 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

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

PACKAGING MARKING



LOGISTICAL INFORMATION



Outer case specifications

Inner case specifications

Item	Size mm	Gross weight kg	QTY/pallet	Size mm	Packaging	QTY
2192S-WH	355 x 235 x 330	1,9	45 cartons (5 layers of 9 cartons)	310 x 110 x 85	Individual bag	4 boxes of 50 pieces

