



RESPIRATORY PROTECTION MASK – Large

2192S-WH EN 149:2001+A1:2009 FFP2 NR D – EN 14683:2014 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:

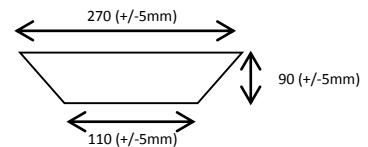
- Use in dusty environment
- To prevent against risky infectious diseases (According to national recommendations)
- Using time: 8 H



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



0082

EN 149:2001+A1:2009

Test	Required level	Laboratory	Report number	Date of Report	Average value
Paraffin Oil penetration	< 6 % after 120mg exposure	APAVE	16.7.0078	23/09/16	5,23 %
NaCl penetration	< 6 % after 120mg exposure				0,73 %
Facial leakage	46 results ≤ 11 % 8 averages in 10 ≤ 8%				Compliant
Air permeability inhalation 30 l/min	≤ 0,7 mbars				0,15 mbar*
Air permeability inhalation 95 l/min	≤ 2,4 mbars				0,65 mbar*
Air permeability exhalation 160 l/min	≤ 3 mbars				1,19 mbar*
Carbon dioxide content	< 1,0 %				0,60 %
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

RESPIRATORY PROTECTION MASK - Large

2192S-WH EN 149:2001+A1:2009 FFP2 NR D – EN 14683:2014 Type IIR

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

NF EN 14683:2014

Test	Standard	Required level	Laboratory	Report number	Date of Report	Value
Bacterial Filtration Efficiency: BFE	EN 14683:2014 (Annex B)	> 98% (Type IIR)	NELSON	961620-S01	10/05/2017	> 99.9%
DELTA P	EN 14683:2014 (Annex C)	< 49 Pa/cm ²	NELSON	961620-S01	10/05/2017	37,17 Pa/cm ²
SPLASH	ISO 22609:2004	≥ 16 kPa	NELSON	864639-S01	21/12/2015	Compliant
Intracutaneous irritation test	ISO 10993-10	no irritation	BIOMATECH	143579	02/02/2012	no irritation
Cytotoxicity	ISO 10993-5	no cytotoxicity	BIOMATECH	143578	02/02/2012	no cytotoxicity
Sensitization	ISO 10993-10 and -10A	Topical application: no sensitization	BIOMATECH	143580	24/02/2012	Topical application: no sensitization
		Intradermal injection: no sensitization	BIOMATECH			Intradermal injection: no sensitization
Microbial cleanliness CFU/g	NF 11737:2006	≤30	MICROSEPT	-	-	Compliant
Using time : BFE + Delta P	EN 14683:2014 (Annex B and C)	> 98% (Type IIR) < 49 Pa/cm ²	NELSON	961620-S01	10/05/2017	8h : > 99.9% 8h : 37,17 Pa/cm ²

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

In accordance with requirements of medical devices Dir.93/42/EEC modified by Dir.2007/47/EC and with EN 14683:2014



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
2192S-WH	355 x 235 x 330	1,9	45 cartons (5 layers of 9 cartons)	310 x 110 x 85	Individual bag	8 boxes of 25 pieces



Medicom

Medicom Healthcare BV
Parallelweg 80a | 3931 MT Woudenberg | The Netherlands
cs@medicom-eu.com | +31 332 866 460