



2092 2092S

RESPIRATORY PROTECTION MASK

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	2092-BL 2092S-BL	2092-WH 2092S-WH
Colour	Blue 	White 

PRODUCT DETAILS

Product name:

Product type:

Outer/Inner layer:

Filter:

Link:

Nosepiece:

Colour:

Unit weight:

Origin:

Mask FFP2 NR D

Single use, non-sterile

Spunbond polypropylene

Meltblown polypropylene

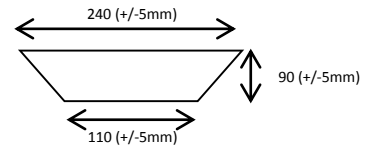
Synthetic elastic

Polypropylene and iron

Blue / White

6,2 g (± 10%)

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

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	864638-S01	17/12/2015	99.9% min
DELTA P	EN 14683:2014 (Annex C)	< 49 Pa/cm ²	NELSON	864638-S01	17/12/2015	37,00 max
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	28/04/2017	8h : > 99.9% 8h : < 37,00 Pa/cm²

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
2092	560 x 260 x 270	4,3	36 cartons (6 layers of 6 cartons)	255 x 110 x 133	Bulk	10 boxes of 50 pieces
2092S	560 x 260 x 270	4,8	36 cartons (6 layers of 6 cartons)	255 x 110 x 133	Individual bag	10 boxes of 50 pieces

