Kolmi®
Made in FRANCE

Technical Data Sheet

M52010 M52010S

RESPIRATORY PROTECTION MASK - OP AIR-PRO® OXYGEN
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

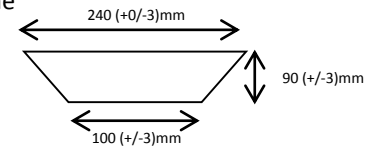
Recommended use :

- Use in dusty environment
- To prevent against risky infectious diseases (According to national recommandations)
- Usage: 8 H

Item	M52010-LV M52010S-LV	M52010-BL M52010S-BL	M52010-PK M52010S-PK	M52010-YL M52010S-YL	M52010-GR M52010S-GR	M52010-WH M52010S-WH
Colour	Lavender	Blue	Pink	Yellow	Green	White

PRODUCT DETAILS

Product name:	**Mask Op-Air Pro® OXYGEN - FFP2 NR D**
Product type:	Single use, non-sterile
Inner/Outer layer:	Non woven Spunbond 100% white polypropylene
Filter:	Meltblown 100% polypropylene
Link:	Synthetic elastic
Nosepiece:	Polypropylene and iron
Colour :	Lavender/Blue/Pink/Yellow/ Green/White
Unit weight :	6,2 g
Origin :	France



CE 0082 NON STERILE 2 LATEX

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 article 11B done by APAVE

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M52010S

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NF EN 14683:2014						
Test	**Standard**	**Required level**	**Laboratory**	**Report number**	**Date of Report**	**Value**
Bacterial Filtration Efficiency: BFE	EN 14683:2014 (Annexe B)	> 98% (Type IIR)	NELSON	864638-S01	17/12/2015	**99.9% min**
DELTA P	EN 14683:2014 (Annexe C)	< 49 Pa/cm²	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 et -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 (Annexe B & C)	> 98% (Type IIR) < 49 Pa/cm²	NELSON	961620-S01	28/04/2017	**8h : > 99.9% 8h : < 37,00 Pa/cm²**

CERTIFICATION

Manufactured under ISO 9001 & EN ISO 13485 certified quality system.
In accordance with requirements of medical devices Dir.89/686/EEC 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

LOGISTIC INFORMATION

Specifications outer case

Item	Size Mm	Gross weight kg	QTY/ pallet
M52010	560 x 260 x 270	4,3	36
M52010S	560 x 260 x 270	4,8	36

Specifications inner case

Size mm	Packaging	QTY
255 x 110 x 133	Bulk	10 boxes of 50 pieces
255 x 110 x 133	Individual bag	10 boxes of 50 pieces

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