Kolmi®
Made in FRANCE

Technical Data Sheet

M52110S-WH

OP-AIR PRO OXYGEN
RESPIRATORY FFP2 MASK with Elastic Head loops
Category III PPE and Class I, Medical Device

FEATURES & BENEFITS

- FFP2 NR D efficiency class filtering mask designed for protect from solid and liquid particles
- Ultrasonic welding

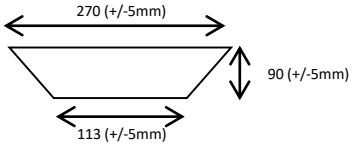
Recommendations :

- Use in a dusty environment
- Protection for those at risk of infectious diseases (According to the national recommendations in force)
- Duration of use: 8 hours maximum (continuous)

Article	M52110S-WH
Color	White ☐

TECHNICAL DIESCRIPTION

Product Name:	**KOLMI – Op-Air Pro Oxygen – Mask FFP2 NR D – Type IIR**
Product Type:	Single-use, non-sterile
Int./Ext. Layers :	Spunbonded polypropylene
Filter:	Melt blown polypropylene
Link:	Synthetic Elastic Head Loops
Nasal bar:	Polypropylene and metal
Size:	Large
Unitary Weight:	6,5 g (± 10%)
Country of Origin:	France



CE 0082 MD NON STERILE LATEX + 5°C + 40°C

EN 149:2001+A1:2009

Performances	Required Level	Laboratory Name	Report Number	Date of Report	Results
Paraffin oil penetration	< 6 % after 120 mg of exposure	APAVE	19.0029	22/01/2019	Pass
NaCl penetration	< 6 % after 120 mg of exposure				Pass
Facial leaks	46 results ≤ 11% 8 averages out of 10 ≤ 8%				Pass
Respiratory resistance Inhalation 30 l/min	≤ 0,7 mbars				Pass
Respiratory resistance Inhalation 95 l/min	≤ 2,4 mbars				Pass
Respiratory resistance exhalation 160 l/min	≤ 3 mbars				Pass
Carbon dioxide content	< 1,0 %				Pass
Flammability	Must not burn or continue to burn for more than 5 seconds after removing the flame				Pass

Protection (D): protection against solid and liquid aerosols, associated with superior resistance to clogging tested with dolomite dust.

* Average test results (Reception status + Simulated port processing)

Annual monitoring according to module D - Reg (EU) 2016/425 performed by APAVE

M52110S-WH

OP-AIR PRO OXYGEN
RESPIRATORY FFP2 MASK with Elastic Head loops
Category III PPE and Class I, Medical Device

NF EN 14683:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT NUMBER	DATE OF REPORT	RESULTS
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/cm²	CENTEXBEL	20.00718.02	20/03/2020	**46,3 Pa/cm² max**
SPLASH	ISO 22609:2004	≥ 16 kPa	CENTEXBEL	20.00718.02	20/03/2020	**PASS**
Cytotoxicity	ISO 10993-5	Absence de cytotoxicité	NELSON	1030830-S01	20/03/2018	**Absence of cytotoxicity**
Irritation cutaneous test	ISO 10993-10	Non irritant	NAMSA	231037	21/06/2017	**Non irritant**
Sensibilization	ISO 10993-10	Non sensibilisant	NAMSA	231038	19/06/2017	**No sensibilization**
Microbial sanitation	NF 11737:2018	≤30 cfu/g	MICROSEPT	1812011-15	14/04/2020	**PASS**
Duration of use BFE + Delta P	EN 14683:2014	≥ 98% (Type IIR) < 49 Pa/cm²	NELSON	961620-S01	28/04/2017	**8h : > 99.9% 8h : < 37,00 Pa/cm²**

PRECAUTIONS FOR USE

The device should only be used on 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.

CERTIFICATION & STANDARDS

Meets the requirements of Regulation (EU) 2017/745 and Regulation (EU) 2016/425.
Complies with the applicable harmonized standards EN 14683 and EN 149.
Manufactured under an ISO 13485 and ISO 9001 certified system.

STORAGE

Normal conditions of conservation and storage: must not be exposed to humidity and sun, must be stored at a temperature between 5°C and 40°C.
Product life: 5 years.

LOGISTICS

Carton Specifications				Dispenser Box Specifications		
Article	**Size mm**	**Unit weight (kg)**	**QTY/ Palette**	**Size mm**	**Cdts**	**QTY**
M52110S-WH	355 x 235 x 330	1,9	45 cartons (4 layers of 10 cartons + 1 layer of 5 cartons)	310 x 110 x 85	Individual Packet	4 dispenser boxes of 50 units

MADE IN FRANCE

KOLMI HOPEN GROUP

Groupe Kolmi Hopen SAS
Bld de la chanterie | 49124 Saint Barthélemy d'Anjou – France
Bld de la chanterie | BP 10059 – 49181 Saint Barthélemy d'Anjou Cedex – France
T : + 33 (0) 241 963 434 | F : + 33 (0) 241 963 453 | sales@kolmi-hopen.com | www.medicom-eu.com