Kolmi®
Made in FRANCE

Technical Data Sheet

M34101F-30
M34301F-30

OP-AIR ONE
MEDICAL MASK TYPE IIR WITH TIES AND ANTI-FOG SYSTEM
Medical Device, Class I

FEATURES & BENEFITS

- Very comfortable and resistant multi-layer nonwoven projection of human liquids under a pressure of 16 kPa
- Very soft non-woven mask ties and edges
- Anatomical folding limiting leakage to the face
- Integrated nose piece
- Fiberglass-free filter
- ISO 8 clean room production (particulate control and microbiological)
- An anti-fog strip acts like a vaporizer to minimize fogging on users' glasses.

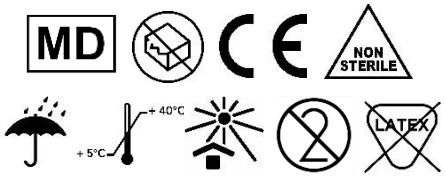
Recommendations :

- Use by operating room personnel for surgeries presenting a risk of splashes of biological fluids
- Use by professionals with sensitive skin
- Use by professionals wearing glasses
- A mask soiled during an operation must be changed

Article	Color
M34101F-30	Blue
M34301F-30	Honey

TECHNICAL DESCRIPTION

Product Name:	**KOLMI – Op-Air One – Mask – Type IIR**
Product Type:	Single-use, non-sterile
Interior Layer:	Wet laid Cellulose
Filter:	PP Complex (Melt blown + Spunbonded)
Exterior Layer:	Spunbonded polypropylene
Link :	Ties
Option:	Anti-fog
Dimensions :	95 mm (± 5 mm) x 175 mm (± 7 mm)
Unitary Weight:	4,5 g (± 10%)
Packaging Conditions:	Dispenser box of 40 units
Country of Origin:	France



Filtration and Comfort Information- NF EN 14683:2019 - Type IIR

TEST	REQUIRED LEVEL	LABORATORY	REPORT NUMBER	DATE OF REPORT	AVERAGE	MINIMUM VALUE	MAXIMUM VALUE
BACTERIAL FILTRATION EFFICIENCY: BFE (%)	≥ 98	NELSON	1242371-S01	02/12/2019	99,2	98,9	99,4
DELTA P (Pa/cm²)	< 60	CENTEXBEL	20.00716.01	27/02/2020	24,1	22,9	25,0
SPLASH RESISTANCE (kPa)	≥ 16	CENTEXBEL	20.00219.01	07/02/2020	PASS		

Microbiological Data (by MICROSEPT)

Assessment of initial microbial contamination according to standards EN 14683: 2019 & ISO 11737: 2018
Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request

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Biological Review- NF EN 14683:2019

	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT NUMBER	DATE OF REPORT	RESULTS
Cytotoxicity	ISO 10993-5	Absence of cytotoxicity	NELSON	1030856-S01	22/03/2018	Absence of cytotoxicity
Irritation	ISO 10993-10	Non irritant	NAMSA	231037	21/06/2017	Non irritant
Sensibilization	ISO 10993-10	No sensibilization	NAMSA	231038	19/07/2017	No sensibilization

PRECAUTIONS

The device should be used on clean, healthy skin only.
Their re-use or prolonged use can produce infection or cross-contamination.
After use, comply with the national regulations set in place for the disposal of the device.

CERTIFICATION & STANDARDS

Complies with the requirements of European Regulation 2017/745 relating to Medical Devices.
Manufactured under an ISO 9001 and ISO 13485 certified system
Complies with applicable harmonized standards EN 14683

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.
Shelf life: 5 years

LOGISTICS

Outer Case Specifications / Dispenser Box Specifications

Article	Size (mm)	Unit weight (Kg)	QTY/ Pallet	Size (mm)	QTY
M34101F-30 **M34301F-30**	333 x 300 x 230	1,6	72 cartons (5 layers od 8 cartons + 8 layers of 4 cartons)	210 x 104 x 140	6 dispenser boxes of 40 units

EAN Codes

Article	Carton	Dispenser Box
M34101F-30	3 662 036 013 415	3 662 036 013 408
M34301F-30	3 662 036 013 613	3 662 036 013 606

MADE IN FRANCE

KOLMI HOPEN GROUP

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