

M24001-30

OP-AIR ONE

M24101-30

MEDICAL MASK TYPE II WITH TIES

M24201-30

Medical Device, Class I

FEATURES & BENEFITS

- High filtration media (polypropylene)
- 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 (particle and microbiological control)

Recommendations:

- Use by caregivers for different types of care
- A mask dirtied during an operation must be changed

TECHNICAL DESCRIPTION

Product Name:	KOLMI – Op-Air One – Mask – Type II
Product Type:	Single-use, non-sterile
Interior Layer:	Wet laid Cellulose
Filter:	Melt blown polypropylene
Exterior Layer:	Spunbonded polypropylene
Link:	Ties
Dimensions:	95 mm (± 5 mm) x 175 mm (± 7 mm)
Unitary Weight:	3,2 g (± 10%)
Packaging Conditions:	Box of 50 units
Country of Origin:	France



Article	Color
M24001-30	White
M24101-30	Blue
M24201-30	Green



Données de Filtration et Confort - NF EN 14683:2019 Type II

Données	Niveau exigé	Nom du laboratoire	Numéro de rapport	Date du Rapport	Moyenne	Valeur minimale	Valeur maximale
EFFICACITE DE FILTRATION: BFE (%)	≥ 98	NELSON	1250736-S01	07/01/2020	99,3	99,0	99,7
DELTA P (Pa/cm²)	< 40	NELSON	1250736-S01	07/01/2020	31,9	31,0	33,0

Données Microbiologiques (Mesures réalisées par le laboratoire MICROSEPT)

Evaluation de la contamination microbienne initiale selon les normes EN 14683:2019 et ISO 11737:2018
Contrôles microbiologiques complémentaires: ASR, E.Coli, Staphylocoques, sur demande

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Biological Evaluation- 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 cutaneous test	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 only be used on clean, healthy skin.

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

Meets the requirements of Regulation (EU) 2017/745

Complies with applicable harmonized standards EN 14683

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**Outer Case Specifications**

Article	Size (mm)	Unit weight (kg)	QTY/ Pallet
M24001-30	400 x 400 x 210	1,6	72 cartons
M24101-30			(5 layers of 8 cartons +
M24201-30			8 layers of 4 cartons)

Dispenser Box Specifications

Size (mm)	QTY
210 x 104 x 140	6 dispenser boxes of 50 units

■ EAN Codes

Article	Carton	Dispenser box
M24001-30	3 662 036 012 463	3 662 036 012 470
M24101-30	3 662 036 012 487	3 662 036 012 494
M24201-30	3 662 036 012 548	3 662 036 012 555



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