

**M34001-30**  
to  
**M34301-30**

**OP-AIR ONE**  
**MEDICAL MASK TYPE IIR WITH TIES**  
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)

## RECOMMENDATIONS:

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



M34101-30

## TECHNICAL DESCRIPTION

Product Name:	<b>KOLMI – Op-Air One – Mask – Type IIR</b>
Product Type:	Single-use, non-sterile
Interior Layer:	Wet laid Cellulose
Filter:	PP Complex (Melt blown + Spunbonded)
Exterior Layer:	Spunbonded polypropylene
Link:	Ties
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

Article	Color
M34001-30	White
M34101-30	Blue
M34201-30	Green
M34301-30	Honey



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

TEST	REQUIRED LEVEL	LABORATORY	REPORT NUMBER	DATE OF REPORT	AVERAGE	MINIMUM VALUE	MAXIMUM VALUE
EFFICACITE DE FILTRATION: BFE (%)	≥ 98	NELSON	1242371-S01	02/12/2019	99,2	98,9	99,4
DELTA P (Pa/cm <sup>2</sup> )	< 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 Information (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.

## CERTIFICATIONS & 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

Article	Size (mm)	Unit weight (kg)	QTY/ Pallet
M34001-30 à M34301-30	333 x 300 x 230	1,6	72 cartons (5 couches de 8 cartons + 8 couches de 4 cartons)

### Dispenser Box Specifications

Size (mm)	QTY
210 x 104 x 140	6 dispenser boxes of 40 masks



### EAN Codes

Article	Carton	Dispenser Box
M34001-30	3 662 036 013 378	3 662 036 013 361
M34101-30	3 662 036 013 392	3 662 036 013 385
M34201-30	3 662 036 012 944	3 662 036 012 951
M34301-30	3 662 036 013 590	3 662 036 013 583

