

M36101V-30

OP'R

MEDICAL MASK TYPE IIR WITH EARLOOPS and VISOR

Medical Device, Class 1

FEATURES & BENEFITS

- Very comfortable multi-layer nonwoven resistant to the projection of human liquids under a pressure of 16 kPa.
- The body of the mask is manufactured in a ISO 8 clean room (particle and microbiological control).
- Type IIR splash protection mask (in accordance with ISO 22609: 2004).
- Bacterial filtration efficiency $\geq 98\%$.
- Polyester visor with anti-fog treatment on both sides


Recommended use :

- Use by operating room personnel for surgeries with a risk of biological fluids projection
- A mask soiled during the intervention must be changed
- Polyester visor allows eyes protection against the risk of potentially contaminated liquids projection



PRODUCT DETAILS

Product name:	KOLMI – Op'R- Mask - Type IIR – With visor
Product type:	Single use, non sterile
Inner layer:	Spunbond polypropylene
Filter :	Meltblown polypropylene
Outer layer:	Spunbond polypropylene
Links :	Earloops
Size :	95 x 175 mm (± 5 mm)
Unit weight:	8,5 g ($\pm 10\%$)
Packaging :	Dispenser box of 25 units
Origin :	France

Item	Color
M36101V-30	Blue 



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

Measurements done by NELSON Laboratory (report available on request)

TEST	Required level	Laboratory	Report number	Date of Report	Average	Minimum value	Maximum value
Bacterial Filtration Efficiency: BFE (%)	≥ 98	NELSON	1264797-S01	17/02/2020	98,6	98,2	98,9
DELTA P (Pa/cm ²)	≤ 60	NELSON	1264797-S01	17/02/2020	20,6	19,6	21,5
SPLASH RESISTANCE (kPa)	≥ 16	NELSON	1264796-S01	17/02/2020	Conform		

Manufacturing Microbiological Information (by MICROSEPT Laboratory)

Bioburden evaluation meets the requirements of EN 14683: 2014 and NF EN 11737: 2006
 Additional microbiological controls: ASR, E.Coli, Staphylococcus, on request

Evaluation Biologique

	Standard	Required level	Laboratory	Report number	Date of Report	Results
Intracutaneous irritation test	ISO 10993-10	non irritation	NAMSA	231037	21/06/2017	non irritation
Cytotoxicity	ISO 10993-5	no cytotoxicity	NELSON	1030856-S01	22/03/2018	no cytotoxicity
Sensitization	ISO 10993-10 et -10A	non sensitization	NAMSA	231038	19/07/2017	non sensitization


CERTIFICATIONS & STANDARDS

Complies with the requirements of European Regulation 2017/745 on Medical Devices
 Manufactured under ISO 13485 certified quality system.
 In conformity with the relevant harmonized standard EN 14683 and EN ISO 14971

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

LOGISTICS INFORMATION

 Outer case specifications				Dispenser box specifications	
Item	Size mm	Gross weight kg	QTY/pallet	Taille mm	QTE
M36101V-30	395 x 246 x 222	1,4	72 cases (8 layers of 9 cases)	222 x 190 x 96	4 dispenser boxes of 25 pièces

 EAN Codes

Item	Outer case	Dispenser box
M36101V-30	3 662 036 018 137	3 662 036 018 144

