

### M34101FV-10 MEDICAL MASK with anti-fog system + visor OP AIR ONE-10® / Type IIR with ties Medical Device, Class I

#### FEATURES & BENEFITS

- New multi-layers nonwoven very resistant to human liquid projection at pressure of 160 mmHg and very comfortable
- Ties and edges in thermobonded nonwoven, very soft
- Anatomic folding limiting inward leakage
- Integrated anti-fog strip and nose piece
- Polyester visor Anti-fog treatment on both sides
- Filter without micro glass
- Production in ISO 8 clean room (particle and microbiological control)

#### Recommended use :

- Use by operating room personnel for surgeries with a risk of biological fluids projection
- Suited to long time surgical operations
- If mask is dirty during operation, therefore change it
- Designed to prevent fogging on glasses
- Polyester visor allows eyes protection against the risk of potentially contaminated liquids projection



#### PRODUCT DETAILS

Product name:	<b>Medical Mask Op Air One-10® – Type IIR with ties with anti-fog system + visor</b>
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Wetlaid Cellulose
Filter:	PP Complex (Meltblown + Spunbond)
Outer layer:	Spunbond polypropylene
Link:	Ties
Option:	Anti-fog + Visor
Colour:	Blue Honeycomb
Size:	95 x 175 mm (± 5 mm)
Unit weight:	8,8 g (± 10%)
Packaging:	Box of 25 units
Origin :	France



#### Filtration and Comfort Information - NF EN 14683:2014 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	1033907-S01	16/04/2018	99,86	99,7	99,9
DELTA P (Pa/cm <sup>2</sup> )	49	NELSON	1033907-S01	16/04/2018	17,50	16,8	18,1
SPLASH RESISTANCE	>=120 mmHg	NELSON	663957	27/11/2012	Pass at 160mmHg		
PFE PARTICULE 0,1µm (%)		NELSON	664776	21/12/2012	99,4	99,3	99,5
Using time efficiency: BFE		NELSON	1033907-S01	16/04/2018	6H: BFE = 99,9		

### 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

### Biological Evaluation - NF EN 14683:2014

	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 and -10A	topical application: no sensitization	NAMSA	231038	19/07/2017	topical application: no sensitization
		intradermal injection: no sensitization				intradermal injection: no sensitization

### CERTIFICATION & STANDARDS

In accordance with requirements of medical devices Dir.93/42/EEC modified by Dir.2007/47/EC

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

### LOGISTICAL INFORMATION



#### Outer case specifications

#### Inner case specifications

Item	Size mm	Gross weight kg	QTY/pallet	Size mm	QTY
M34101FV-10	395 x 246 x 222	1,5	72 cartons (8 layers of 9 cartons)	222 x 190 x 96	4 boxes of 25 pieces



#### EAN Codes

Item	Outer case	Inner case
M34101FV-10	3 662 036 005 311	3 662 036 004 994

