

**M24001-10**      **SURGICAL MASK**  
**M24101-10**      **OP AIR One-10® / Type II with ties**  
**M24201-10**      **Medical Device, Class I**

### FEATURES & BENEFITS

- High filtration with filter media (polypropylene)
- Ties and edges in thermobonded nonwoven, very soft
- Anatomic folding limiting inward leakage
- Integrated anti-fog nose piece
- Filter without micro glass
- Production in ISO 7 clean room (particle and microbiological control)

### Recommended use :

- Use by operating room personnel for surgeries, without risk identified for the wearer (projection of biological fluids)
- Suited to long time surgical operations
- If mask is dirty during operation, therefore change it



### PRODUCT DETAILS

Product name: **Surgical Mask Op Air One-10® – Type II with ties**  
 Product type: Single use, non-sterile  
 Inner layer: White Hypoallergenic Wetlaid Cellulose  
 Filter: PP Complex (Meltblown + Spunbond)  
 Link: Ties  
 Colour: White / Blue / Green  
 Size: 95 x 175 mm  
 Unit weight: 3,2 g  
 Packaging: Box of 50 units  
 Origin : France

Item	Colour
M24001-10	White
M24101-10	Blue
M24201-10	Green



### Filtration and Comfort Information - NF EN 14683:2014 Type II

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	614278	13/01/2012	99,5	99,4	99,7
DELTA P (Pa/cm <sup>2</sup> )	29,4	NELSON	614278	13/01/2012	12,0	11,8	12,2
PFE PARTICLE 0,1µm		NELSON	614275	16/01/2012	99,0	99,0	99,1
Using time efficiency: BFE		NELSON	614274	13/01/2012	6H: BFE = 99,30%	99,1	99,8

### 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

**M24001-10****SURGICAL MASK****M24101-10****OP AIR One-10® / Type II with ties****M24201-10****Medical Device, Class I****Biological Evaluation - NF EN 14683:2014**

	Standard	Required level	Laboratory	Report number	Date of Report	Results
Intracutaneous irritation test	ISO 10993-10	non irritation	BIOMATECH	143579	03/02/2012	non irritation
Cytotoxicity	ISO 10993-5	no cytotoxicity	BIOMATECH	143578	02/02/2012	no cytotoxicity
Sensitization	ISO 10993-10 et -10A	topical application: no sensitization	BIOMATECH	143580	24/02/2012	topical application: no sensitization
		intradermal injection: no sensitization	BIOMATECH			intradermal injection: no sensitization

**CERTIFICATION**

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

**LOGISTIC INFORMATION**

**Specifications  
outer case**

Item	Size mm	Gross weight kg	QTY/pallet
M24001-10 M24101-10 M24201-10	340 x 305 x 230	1,52	72

**Specifications  
inner case**

Size mm	QTY
210 x 104 x 140	6 boxes of 50 pieces



**EAN Codes**

Item	Outer case	Inner case
M24001-10	3 662 036 003 072	3 662 036 000 422
M24101-10	3 662 036 003 126	3 662 036 000 477
M24201-10	3 662 036 003 188	3 662 036 000 538



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