

### M27011

**MEDICAL MASK LASER large size**  
**OP AIR® / Type II with ties**  
 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 8 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:	<b>Medical Mask Laser Op Air® – Type II with ties large size</b>
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	Meltblown polypropylene
Outer layer:	Spunbond polypropylene
Link:	Ties
Colour:	White
Size:	95 x 195 mm (± 5 mm)
Unit weight:	3,9 g (± 10%)
Packaging:	Box of 50 units
Origin :	France



#### 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	961622-S01	10/05/2017	99,4	99,1	99,9
DELTA P (Pa/cm²)	29,4	NELSON	961622-S01	10/05/2017	17,1	16,8	17,8
Using time efficiency: BFE		NELSON	961622-S01	10/05/2017	4H: BFE = 99,40%		

#### 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

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### 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	1030858-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

Item	Size mm	Gross weight kg	QTY/pallet
M27011	333 x 300 x 228	1,8	72 cartons (8 layers of 4 cartons + 5 layers of 8 cartons)

#### Inner case specifications

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



#### EAN Codes

Item	Outer case	Inner case
M27011	3 662 036 003 218	3 662 036 000 569

