

M35111-20

M35311-20

### MEDICAL MASK

OP AIR-10® / Type IIR with earloops

Medical Device, Class I

#### FEATURES & BENEFITS

- New multi-layers nonwoven very resistant to human liquid projection at pressure of 120 mmHg and very comfortable
- 2 comfortable large earloops
- Very soft polypropylene nonwoven edge
- Anatomic folding limiting inward leakage
- Integrated anti-fog nose piece
- Filter without micro glass
- Production in ISO 8 clean room (particle and microbiological control)





M35111-20

#### 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

#### PRODUCT DETAILS

Product name:	<b>Medical Mask Op Air-10® – Type IIR with earloops</b>
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	PP Complex (Meltblown + Spunbond)
Outer layer:	Spunbond polypropylene
Link:	Earloop
Size:	90 x 175 mm (± 5 mm)
Unit weight:	4 g (± 10%)
Packaging:	Box of 50 units
Origin :	France

Item	Colour
M35111-20	Blue 
M35311-20	Orange 



#### 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	1015921-S01	01/02/2018	99,81	99,7	99,9
DELTA P (Pa/cm <sup>2</sup> )	49	NELSON	1015921-S01	01/02/2018	21,39	20,3	22,0
SPLASH RESISTANCE	>=120 mmHg	NELSON	1015922-S01	01/02/2018	Pass at 120 mmHg		
PFE PARTICULE 0,1µm (%)		NELSON	1015920-S01	05/02/2018	99,50	99,4	99,5
Using time efficiency: BFE		NELSON	1015921-S01	01/02/2018	6H: BFE = 99,7		

#### 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	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
M35111-20 M35311-20	400 x 400 x 220	4,3	60 cartons (10 layers of 6 cartons)

**Inner case specifications**

Size mm	QTY
211 x 97 x 97	16 boxes of 50 pieces



**EAN Codes**

Item	Outer case	Inner case
M35111-20	3 662 036 007 025	3 662 036 007 124
M35311-20	3 662 036 007 032	3 662 036 007 131

