

M15301-20 **MEDICAL MASK**
M15311-20 **OP AIR-20® / Type I with earloops**
M15321-20 **Medical Device, Class I**

FEATURES & BENEFITS

- High filtration with filter media (polypropylene)
- 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)




Recommended use :

- Use by patients or individuals in an epidemic or pandemic situation



PRODUCT DETAILS

Product name: **Medical Mask Op Air-20® – Type I with earloops**
 Product type: Single use, non-sterile
 Inner layer: PP Complex (Meltblown + Spunbond)
 Outer layer: Spunbond polypropylene
 Link: Earloops
 Size: 90 x 175 mm (± 5 mm)
 Unit weight: 2,8 g (± 10%)
 Packaging: Box of 60 units
 Origin: France

Item	Colour
M15301-20	White 
M15311-20	Blue 
M15321-20	Green 



Filtration and Comfort Information - NF EN 14683:2014 Type I

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 (%)	95	NELSON	820184	15/05/2015	99,3	99,1	99,5
DELTA P (Pa/cm ²)	29,4	NELSON	820184	15/05/2015	16,1	15,7	16,8

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

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	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	1030854-S01	16/03/2018	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
M15301-20 M15311-20 M15321-20	400 x 400 x 220	3,6	60 cartons (10 layers of 6 cartons)

Inner case specifications

Size mm	QTY
211 x 97 x 97	16 boxes of 60 pieces



EAN Codes

Item	Outer case	Inner case
M15301-20	3 662 036 006 950	3 662 036 007 056
M15311-20	3 662 036 006 974	3 662 036 007 070
M15321-20	3 662 036 006 998	3 662 036 007 094

