

M95241-10 MEDICAL MASK « KID (1-5 years) » OP AIR-10® / Type II with earloops Medical Device, Class I

FEATURES & BENEFITS

- High filtration with filter media (polypropylene)
- Anatomic folding limiting inward leakage
- Very soft polypropylene nonwoven edge
- Instruction for use is under the cover of the box
- Nose piece: 2 coated steel wire with polypropylene
- Elastane earloop knitted with polypropylene
- Filter without micro glass
- Production in ISO 8 clean room (particle and microbiological control)



Recommended use :

- Use by infectious patients (1 to 5 years) during their displacements within the hospital
- For pediatric services and childhood surgery
- Change the mask for each displacement

PRODUCT DETAILS

Product name:	Medical Mask Op Air-10® – Type II with earloops KID (1-5 years)
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	PP Complex (Meltblown + Spunbond)
Link:	Earloops
Colour:	Blue
Size:	95 x 115 mm (± 5 mm)
Unit weight:	1,5 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	1033927-S01	16/04/2018	98,66	98,2	99,0
DELTA P (Pa/cm²)	29,4	NELSON	1033927-S01	16/04/2018	16,34	15,6	17,5
PFE PARTICULE 0,1µm (%)		NELSON	614275	16/01/2012	98,96	98,9	99,0
Using time efficiency: BFE		NELSON	1033927-S01	16/04/2018	4H: BFE = 98,20%		

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
M95241-10	400 x 300 x 175	1,6	72 cartons (6 layers of 12 cartons)

Inner case specifications

Size mm	QTY
157 x 100 x 90	12 boxes of 50 pieces



EAN Codes

Item	Outer case	Inner case
M95241-10	3 662 036 005 632	3 662 036 007 261

