

M95121-10

BLUE PEDIATRICS STANDARD SURGICAL MASK OP AIR-10® KID (5-12 years) / 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 7 clean room (particle and microbiological control)



Recommended use :

- Use by infectious patients (5 to 12 years) during their displacements within the hospital
- For pediatric services and childhood surgery
- Change the mask for each transfer

PRODUCT DETAILS

Product name:	Standard Surgical Mask OP AIR-10® Kid (5-12 years) - Type II with earloops
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	PP Complex (Meltblown + Spunbond)
Link:	Earloops
Colour :	Blue
Size:	95 x 145 mm
Unit weight:	1,8 g
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	614278	13/01/2012	99,34	99,3	99,4
DELTA P (Pa/cm ²)	29,4	NELSON	614278	13/01/2012	13,08	12,2	13,8
PFE PARTICLE 0,1µm		NELSON	614275	16/01/2012	98,96	98,9	99,0
Using time efficiency: BFE		NELSON	614274	13/01/2012	5H: BFE = 98,50%	98,5	99,4

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	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
M95121-10	330 x 330 x 220	1,6	55

Specifications inner case

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



EAN Codes

Item	Outer case	Inner case
M95121-10	3 662 036 007 247	3 662 036 007 254

