

M21001-10	SURGICAL MASK
M21101-10	OP AIR-10® / Type II with ties
M21201-10	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 7 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:	Surgical Mask Op Air-10® – Type II with ties
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	PP Complex (Meltblown + Spunbond)
Link:	Ties
Colour:	White / Blue / Green
Size:	95 x 175 mm
Unit weight:	3,2 g
Packaging:	Box of 50 units
Origin :	France

Item	Colour
M21001-10	White
M21101-10	Blue
M21201-10	Green



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/cm²)	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

M21001-10**SURGICAL MASK****M21101-10****OP AIR-10® / Type II with ties****M21201-10****Medical Device, Class I****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
M21001-10 M21101-10 M21201-10	340 x 305 x 230	1,26	72

**Specifications
inner case**

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



EAN Codes

Item	Outer case	Inner case
M21001-10	3 662 036 002 990	3 662 036 000 347
M21101-10	3 662 036 003 010	3 662 036 000 361
M21201-10	3 662 036 003 034	3 662 036 000 385



KOLMI HOPEN®

KOLMI HOPEN SASU

Bld de la chanterie | 49124 Saint Barthélemy d'Anjou – France

Bld de la chanterie | BP 10059 – 49181 Saint Barthélemy d'Anjou Cedex – France

T : 33 (0) 241 963 434 | F : + 33 (0) 241 963 453 | sales@kolmi-hopen.com | www.h-open.com