

M21200-10SU GREEN SURGICAL MASK OP AIR-10® / Type II with ties

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:	2 bags of 100 individual polybags
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

Responsibilities:

In Europe, if this article is intended for the medical sector and meets the definition of "medical device", the distributor must apply Directive 93/42/EEC (+ its amendments) transcribed in the national legislation of the European member states. The distributor becomes the "manufacturer" and is responsible for the CE marking. KOLMI HOPEN will be able to provide you the necessary documents to prepare your technical file.

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
M21200-10SU	295 x 260 x 215	1,00	96

Specifications polybag

QTY
2 bags of 100 individual polybags

