Kolmi®
Made in FRANCE

Technical Data Sheet

M21200-10ST30

GREEN STERILE SURGICAL MASK
OP AIR-10® / Type II with ties
Medical Device, Class Is

FEATURES & BENEFITS

- High filtration with filter media (polypropylene)
- The masks were sterilized with ethylene oxide by the INNOSET laboratory, certified by the notified body LNE
- 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)

STERILE EO

Recommended use :

- Sectors: Laboratories (Biomedical Analysis, Research), Health (Surgery)
- 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:	**Sterile 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:	Green
Size:	95 x 175 mm
Unit weight:	3,2 g
Packaging:	10 bags of 30 individual polybags
Origin:	France

CE 2 LATEX

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

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Sterilization – NF EN ISO 10993-7
(Analysis by the Laboratory of Environmental Analysis, 12/05/2016)

In conformity with with the NF EN ISO 10993-7 standard for residues of ethylene oxide (<1 mg/l)
In conformity with the NF EN ISO 10993-7 standard for residues of ethylene hydrochloride (<5 mg/l)
This product contains less than 0.02 mg of ethylene oxide and less than 0.1 mg of ethylene hydrochloride

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: 3 years

LOGISTIC INFORMATION

Specifications outer case				Specifications polybag
Item	**Size mm**	**Gross weight kg**	**QTY/ pallet**	**QTY**
M21200-10ST30	390 x 390 x 280	3,00	36	10 bags of 30 individual polybags

MADE IN FRANCE

afaq ISO 9001 Qualité AFNOR CERTIFICATION

afaq ISO 13485 Santé Médical AFNOR CERTIFICATION

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