

# Technical Data Sheet

Made in FRANCE

M14300-20  
M14310-20  
M14320-20

## STANDARD SURGICAL MASK OP AIR-10® / Type II with earloops

### FEATURES & BENEFITS

- High filtration with filter media (polypropylene)
- 2 comfortable large earloops
- Very soft polypropylene nonwoven edge
- 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 caregiver for different types of care
- If mask is dirty during operation, therefore change it
- Suitable for the movement of contagious patients (adults) within the hospital



### PRODUCT DETAILS

Product name:	<b>Standard Surgical Mask Op Air-10® – Type II with earloops</b>
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	PP Complex (Meltblown + Spunbond)
Link:	Earloops
Colour:	White / Blue / Green
Size:	95 x 175 mm
Unit weight:	2,8 g
Packaging:	Box of 60 units
Origin :	France

Item	Colour
M14300-20	White
M14310-20	Blue
M14320-20	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

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**STANDARD SURGICAL MASK**  
**OP AIR-10® / Type II with earloops**

**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 and -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**

**Specifications  
inner case**

Item	Size mm	Gross weight kg	QTY/pallet	Size mm	QTY
M14300-20 M14310-20 M14320-20	400 x 400 x 220	3,57	60	211 x 97 x 97	16 boxes of 60 pieces

**EAN Codes**

Item	Outer case	Inner case
M14300-20	3 662 036 006 813	3 662 036 006 875
M14310-20	3 662 036 006 837	3 662 036 006 899
M14320-20	3 662 036 006 851	3 662 036 006 912



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