






Made in FRANCE

**PRODUCT CHARACTERISTICS**

<b>MATERIAL</b>	3-ply high filtration with filter media (polypropylene)	  
	White outer coverstock	
all raw materials come from European countries to limit CO2 during transportation	White hypoallergenic inner coverstock	<b>RECOMMENDED USE:</b> <b>Using for different surgical operations and care.</b> <b>Suited to long time surgical operations.</b> <b>if mask is dirty during operation, therefore change it.</b>
	Filter : meltblown polypropylene without micro glass	
	Ties and edges in thermobonded nonwoven, very soft	
	Anatomic folding limiting inward leakage	
	Integrated anti- FOG STRIP and nose piece.	

**MECHANICAL INFORMATION** Measurements done by Kolmi Laboratory

TEST	Standard	Average	Unit	Tolerance
filtering complex mass by unit area	NF EN ISO 9073-1	74	g/sqm	+/-5%
Tensile strength resistance of ties welding on the mask	NF EN ISO 29073-3	12	N	+/-25%
Tensile strength resistance of ties on the mask	NF EN ISO 29073-3	50	N	+/-5%
Particle emission rate (Helmke Garment cleanliness Classification per IEST -RP-CC:3 ( particle $\geq 0,5 \mu\text{m}$ ) Categorie I I		355	Nb de particule/m <sup>2</sup>	< 500

**FILTRATION and COMFORT INFORMATION** NF EN 14683 : 2006 Type II

Measurements done by NELSON Laboratories INC (Masks certificates and measures are available upon request)

	Standard	required level	Laboratory	Report Number	Date of Report	Average	Minus value	Maximum value
<b>Bacterial Filtration Efficiency: BFE</b>	NF EN 14683 TYPE II	> 98%	NELSON	614278	Janv/2012	99,34 %	99,3 %	99,4 %
<b>DELTA P</b>	NF EN 14683 TYPE II	< 29,4 Pa	NELSON	614278	Janv/2012	13.08 Pa	12.2 Pa	13.8 Pa
<b>PFE PARTICLE 0,1<math>\mu\text{m}</math></b>	ASTM 2299		NELSON	614275	Janv/2012	98.96 %	98.89 %	99 %
<b>Using time efficiency: : BFE</b>	NF EN 14683/2006	6 H	NELSON	614274	Janv/2012	98.5		



**MANUFACTURING MICROBIOLOGICAL INFORMATION ( by Microsept Laboratory)**

Bioburden evaluation meets the requirements of NF ISO 11737/2006 STANDARD: Additional microbiological controls: ASRE;COLI, STAPHYLOCOCCUS

**BIOLOGICAL EVALUATION**

	Standard	required level	Laboratory	report Number	Date of Report	Results
<b>Intracutaneous irritation test</b>	ISO 10993-10	non irritation	BIOMATECH	143579	02/02/2012	non irritation
<b>Cytotoxicity</b>	ISO 10993-5	no cytotoxicity	BIOMATECH	143578	02/02/2012	no cytotoxicity
<b>Sensitization: extract: 0,9% NaCl &amp; sesame oil</b>	ISO 10993-10 et -10A	topical application: no sensitization	BIOMATECH	143580	24/02/2012	topical application: no sensitization
		intra-dermal injection: no sensitization	BIOMATECH			no sensitization

**PACKAGING (indicative values)**

	Size	quantity	Weight	Volume	Storage conditions
<b>Mask</b>	95 x 175 mm	1	4,7 g		  <85%
<b>Dispenser</b>	210 x 107 x 142 mm	50	257 g	3,20 dm <sup>3</sup>	
<b>Case</b>	333 x 300 x 228 mm	300 units (6 dispensers of 50)	1,7 Kg	23 dm <sup>3</sup>	
<b>Pallet</b>	0,80 x 1,20 x 1,97 m	72 cases 8 rows of 4 cases + 5 rows of 8 cases	137 kg	1,9m <sup>3</sup>	

**CE** IN ACCORDANCE WITH REQUIREMENTS OF MEDICAL DEVICES 93/42/CEE MODIFIED BY 2007/47 CE  
keeping under control of manufacturing procedures - Traceability - Risk analysis

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