

PRODUCT SPECIFICATION

Product name	FluidProtect face mask
Range	Universal
Marking	Product name, Universal logo, code ref., lot number, quantity, CE mark, expiry date, latex free and single use symbols.
Material	Particle Filtration Efficiency (PFE) down to 0.1 micron at $\geq 99\%$ Bacterial Filtration Efficiency (BFE) down to 3 microns at $\geq 99\%$

Product code	Description
UN49205	Anti-fog band with ties
UN49210	Anti-fog Band with ear loops
UN49245	Anti-fog mask visor and ties
UN49250	Anti-fog with visor and loops

Primary use	To provide protection for medical staff. Suitable for general patient care and procedures where there is a risk of contamination during splash or spray procedures.
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Packaging			Fit
Product code	Qty per inner	Qty per outer	
UN49245	25	100	Ties
UN49250	25	100	Earloops
UN49205	50	300	Ties
UN49210	50	300	Earloops

Quality certification	ISO 13485
Conformity to guidelines	Class 1 – Medical Device Directive 93/42/EEC
Conformity to standards	EN14683 Type IIR. ASTM F2100-11 Level 3.
Storage conditions	Store in a cool dry place away from heat and direct sunlight
Shelf life	3 years if stored as recommended above
Additional information	<p>Tested according to ASTM F1862 Bacterial Filtration efficiency (BFE) $\geq 98\%$ Differential pressure < 49.0 Pa Splash resistance pressure ≥ 160 mm of Hg</p> <p>The product is tested to Flammability type A, Class 1 – No flame spread.</p> <p>The product is latex; nickel and cadmium free. The product is non sterile.</p>
<i>Medical Device and Reporting System:</i> According to the official criteria of MDD, incidents caused by this device must be reported immediately to our offices.	

REVISION:	7.0	DATE	10/05/2016	AUTHOR	J Bertran
NOTES:	Detailed the EN14683 tests results.				

The information provided within this Data Sheet is correct as of last revision but it is subject to change without notice.

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