

PRODUCT SPECIFICATION

Product Name	FluidProtect Type IIR Procedure Facemasks with Ear-loops
Protect Ref	UN49212
Markings to labelling	<ul style="list-style-type: none"> Product Description and Ref, Lot Number, CE Mark and manufacturing address Manufacture and Expiry Date, Latex Free symbol Non-Sterile and Single use symbols EN 14683 standard and type reference
Sterilisation method	Non-Sterile

Primary Use

Intended to be used to protect the user where there is a risk of fluid contamination during splash or spray prone procedures.

Material		Key Features
Layer 1 (outer)	Blue Polypropylene	Water Repellent
Layer 2 (middle)	White, Meltblown	High Filtration BFE >99%
Layer 3 (inner)	White Polypropylene	Soft and Comfortable
Ear-loops	Elastic Fibre	Latex Free
Nose Bridge	Polyethylene with single wire	Easy to adjust

Packaging

Units per Inner	50pcs	Inner Box Dimension	18x9x10cm
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Quality certification	ISO13485
Conformity to guidelines	Class I – European Medical Device Regulation 2017/745
Conformity to standards	The products conform to standard BS EN 14683:2019 BFE ≥98% Differential Pressure <60 Pa/cm ² Splash Resistance ≥16kPa Microbial Cleanliness ≤30cfu/g
Storage conditions	Store in a cool dry place away from heat and direct sunlight
Shelf life	Refer to product packaging
Additional information	The product is latex free and non-sterile.
<i>Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.</i>	

REVISION:	3.0	DATE	14/05/2020	AUTHOR	A Gidley
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The information provided within this Data Sheet is correct as of last revision but it is subject to change without notice.

365 Healthcare T: +44 (0) 1905 778365 W: www.365healthcare.com	Unit 1, West Bank, Berry Hill Industrial Estate Droitwich Spa Worcestershire, WR9 9AX
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