

Product Specifications Sheet

Specification Sheet No	SSN-MASK(NS)-003			
Product Name	FluidProtect with Ear-loops			
Product Description	Type IIR Procedure Facemasks			
Range	365 Healthcare			
Manufacturer	Mediq Healthcare UK Ltd			
Material	Polypropylene (Outer and inner layer), Meltblown (middle layer), Urethane Elastic Fibre (Ear-loops), Polyethylene with single iron wire (Nose bridge)			
Sterilisation	Non-sterile			
Issue Date	21st May 2024	Version No	R02	

Intended use	Intended to be used to protect the user when there is a risk of fluid contamination during splash or spray prone procedures.
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Packaging				
Product code	Colour	Dimension (cm)	Qty- Inner	Qty – Shipper Carton
UN49212	Blue	Mask – 17.5 cm x 9.5 cm (±5%) Ear Loop – 17.5cm ±0.3	50 Pcs	1000 Pcs (20 x 50)

Quality Certification	ISO 13485		
Device Classification	I	Rule	1
Conformity Route	Medical Devices Regulation (EU) 2017/745 Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)		
Storage conditions	Store in a cool dry place away from heat and direct sunlight		
Shelf life	3 years if stored as recommended		
Contraindications/Warnings	None		
Markings	Product Description and Ref , Lot Number and QTY , CE Mark and manufacturing address , Manufacture and Expiry Date, Latex Free, Non-Sterile and Single use symbols , EN 14683 standard and type reference		
Additional information	This product is latex free.		
Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.			

Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 rd April 2024

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

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Amendment Record

This procedure is reviewed to ensure its continuing relevance to the system and process that it describes. A record of contextual additions or omissions is given below. This revision history lists all changes to this document, the date of each revision, and the reason for each revision.

Revision Number	Revision Date	Reason for Revision	Updated by
R01	23/06/2023	Update to Mediq UK Brand replacing DSN 834	Racheal Begg
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong

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