

# Product Specifications Sheet

<b>Specification Sheet No</b>	SSN-MASK(NS)-002		
<b>Product Name</b>	Facemasks & Respirators		
<b>Product Description</b>	FluidProtect Anti-fog Surgical Facemask with Ties (Type IIR) FluidProtect Anti-fog Surgical Facemask with ear loops (Type IIR) FluidProtect Anti-fog Surgical Facemask with Visor and Ties (Type IIR) FluidProtect Anti-fog Surgical Facemask with Visor, Ear Loops (Type IIR)		
<b>Range</b>	Universal		
<b>Manufacturer</b>	Mediq Healthcare UK Ltd		
<b>Material</b>	Outer or observer layer: 28±2gsm Fluid resistant Spunbond Polypropylene fibre (hydrophobic) 2nd layer: 24±2 gsm fluid resistant perforated PE film (PPF) Filter or 3rd Layer: 25±2 gsm 100%PP Meltblown filtration fibre (hydrophobic) Inner Layer: 20±2gsm fluid resistant Spunbond Polypropylene fibre (hydrophobic) Ear loops (UN49210 & UN49250): Spandex polyurethane coated with nylon Ties (UN49205 & UN49245) : 35±2gsm 100% PP Spunbond (hydrophobic)		
<b>Sterilisation</b>	Non-sterile		
<b>Issue Date</b>	23 <sup>rd</sup> June 2023	<b>Version No</b>	R01



UN49205



UN49210



UN49245



UN49250

<b>Intended use</b>	Intended to be placed over the mouth and nose of a healthcare worker to permit normal breathing whilst protecting the patient from the transfer of particles and contamination during medical procedures and surgery. Type IIR mask are fluid resistant.
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Packaging							
Product code	Remark	Colour	Mask Body Dimension (mm) L x W	Ear Loop/Ties length (mm)	Items per Pack	Qty – Inner	Qty – Shipper Carton
UN49205	With ties	Orange	175 x 95 (±2)	900±5	6	50	300
UN49210	Ear loops			165 ±5	6	50	300
UN49245	Visor, ties			900 ±5	4	25	100
UN49250	Visor, Ear loops			165 ±5	4	25	100

Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004	Product Specification Sheet	Ashley Miller	Racheal Begg	R01	12 <sup>th</sup> June 2023

<b>Quality Certification</b>	ISO 13485		
<b>Device Classification</b>	I	<b>Rule</b>	1
<b>Conformity Route</b>	Medical Devices Regulation (EU) 2017/745 Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)		
<b>Storage conditions</b>	Store in a cool dry place away from heat and direct sunlight		
<b>Shelf life</b>	5 years if stored as recommended		
<b>Contraindications/Warnings</b>	None		
<b>Markings</b>	Universal Logo, Product name, Ref, Quantity, Lot number, Manufacturing date, Expiry date, Barcode, Manufacturer name & Address, Non-sterile, CE Mark, Single use, Latex free, medical device, keep dry, keep away from sunlight, EC-REP		
<b>Additional information</b>	Microbial Cleanliness $\leq 30$ cfu/g, splash resistance pressure $\leq 16.0$ kPa		
<i>Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.</i>			

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 829	Racheal Begg

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DMS 04-004	Product Specification Sheet	Ashley Miller	Racheal Begg	R01	12 <sup>th</sup> June 2023