

Product Specifications Sheet

Specification Sheet No	SSN-MASK(NS)-001			 UN41810
Product Name	Facemasks & Respirators			
Product Description	UniPotect Surgical Facemasks with Ties (Type IIR) UniPotect Surgical Facemasks with Ear Loops (Type IIR) UniProtect Anti-fog Surgical Facemask with Ties (Type IIR)			
Range	Universal			 UN42815  UN43910
Manufacturer	Mediq Healthcare UK Ltd			
Material	Outer or Observe layer: Fluid resistant Spunbond Polypropylene fibre (hydrophobic) Filter or Middle Layer: Meltblown filtration fibre (hydrophobic) Inner Layer: Silk like, ultra-soft ES fibre for sensitive skin (hydrophobic) Ties: 100% PP Spunbond (hydrophobic) Ear loops: Spandex polyurethane coated with nylon thread Anti-fog Foam: Ultra soft anti fog foam on inner lay			
Sterilisation	Non-Sterile			
Issue Date	20 th Nov 2024	Version No	R03	

Intended use	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
UN41810	With Ties	Blue	175 x 95 (±2)	900 ±5	6	50	300
UN42815	With Ear Loops			165 ±5			
UN43910	Anti-Fog with Ties			900 ±5			

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	There are no contraindications if used in the correct environment/setting.		
Markings	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		

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

Additional information	Conforms to EN ISO 14683:2019 Type IIR standard, BFE $\geq 98\%$, DP $< 60\text{Pa/cm}^2$ Microbial Cleanliness ≥ 30 cfu/g, splash resistance pressure $\geq 16.0\text{kPa}$
<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 828	Racheal Begg
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong
R03	20/11/2024	Update the product life to 3 years according to supplier specification	Jack Wong

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