

## **Product Specifications Sheet**

Specification Sheet No	SSN-EGL(S)-004				
Product Name	Examination Glov				
Product Description	Nitrile Blue Powe	Nitrile Blue Powder Free Gloves			
Range	Premier	MEDILIA  NITRILE BLUE  STERILE MEDICAL GLOVES  ET POPULS  OTT 430 Pars			
Manufacturer	Mediq Healthcar				
Material	Nitrile				
Sterilisation	EO Sterile				
Issue Date	7 <sup>th</sup> Sept 2023	Version No	R01		



Intended use	Intended to be worn during medical examinations to prevent contamination between patients and users.
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	Packaging								
Product code	Size	Width	Colour	Length (mm)	Palm Thickness (mm)	Force at break	Items Per Pack	Qty- Inner	Qty – Shipper Carton
P2759/S	Extra Small	≤80							
P2760/S	Small	80±10							
P2761/S	Medium	95±10	Blue	≥240	0.09±0.05	≥6.0	1 pair	50	200
P2762/S	Large	110±10							
P2763/S	Extra Large	≥110							

Quality Certification	ISO 13485				
Device Classification	Class Is	Rule	5		
Conformity Route	Medical Device Regulations (EU) 2017/745 Medical Devices Regulations 2002 (SI2002/618, as amended) (UK MDR 2002)				
Storage conditions	Store in a cool dry place away from heat, direct sunlight, dust free & avoid ventilation				
Shelf life	3 Years from the date of manufacturer, if stored as recommended				
Contraindications/Warnings	There are no contraindications if used in the correct environment/setting.				
Markings	Premier logo, Product name, Quantity, Ref, Nitrile, Colour, Powder free, Size, CE Mark, Latex free, Single use, Medical device, EO Sterile, keep dry, keep away from sunlight, Do not use if package is damaged, Manufacturer name & address, EC-REP Barcode, Lot, Manufacturing date & Use by date				
Additional information	Finger textured, Ambidextrous, Latex Free				
Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.					

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

1	Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
	DMS 04-004-02	Product Specification Sheet	Ashley Miller	Racheal Begg	R01	12 <sup>th</sup> June 2023



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## **Amendment Record**

This procedure is reviewed to ensure its continuing relevance to the system and process that is 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	07/09/2023	Update to Mediq UK Brand Replacing DSN 572	Racheal Begg

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