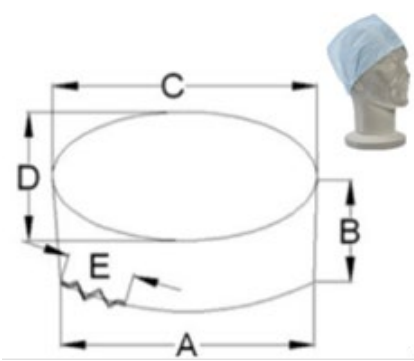


Product Specifications Sheet

Specification Sheet No	SSN-SCAP(NS)-003		
Product Name	Surgical Caps		
Product Description	Theatre Cap with Elasticated Back (Plain Material)		
Range	Universal		
Manufacturer	Mediq Healthcare UK Ltd		
Material	Non-woven Polypropylene 25g/m ²		
Sterilisation	Non-sterile		
Issue Date	26 th June 2023	Version No	R01



Intended use	A non-sterile head covering designed as a cap intended to be worn by surgical staff during an operation to protect both the patient and themselves from the transfer of microorganisms, bodily fluids, and particulate material.
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Packaging						
Product code	Colour	Dimension (cm)			Qty- Inner	Qty – Shipper Carton
UN91230/PL	Blue	A	Full cycle length with stretched elastic	63 (±2)	100	600
		B	Cap height	13 (±1)		
		C	Length of Cap top	20 (±1)		
		D	Width of Cap top	20 (±1)		
		E	Elastic Length	7-8 (±1)		
		Stretched elastic length				
UN91231/PL	Green	A	Full cycle length with stretched elastic	63 (±2)	100	600
		B	Cap height	13 (±1)		
		C	Length of Cap top	20 (±1)		
		D	Width of Cap top	20 (±1)		
		E	Elastic Length	7-8 (±1)		
		Stretched elastic length				
UN91232/PL	Pink	A	Full cycle length with stretched elastic	63 (±2)	100	600
		B	Cap height	13 (±1)		
		C	Length of Cap top	20 (±1)		
		D	Width of Cap top	20 (±1)		
		E	Elastic Length	7-8 (±1)		
		Stretched elastic length				

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



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	Universal Logo, Ref code, Quantity, Image, Product name, Colour, CE Mark, Single use, Latex free, medical device, Non-sterile, keep dry, keep away from sunlight, Barcodes, Recyclable, Lot, Manufacturing & Expiry date, EC-REP, Manufacturer name and address		
Additional information	This product is latex free		
<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	26/06/2023	Update to Mediq UK Brand replacing DSN 023	Ashley Miller

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