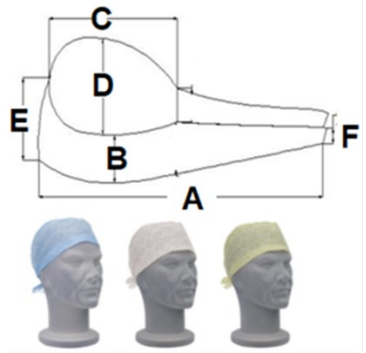


Product Specifications Sheet

Specification Sheet No	SSN-SCAP(NS)-010			
Product Name	Surgical Caps			
Product Description	Theatre Cap – Tie Backs (Patterned Material)			
Range	Universal			
Manufacturer	Mediq Healthcare UK Ltd			
Material	Fibre: 69% Viscose, Binder: 21% Polymer based on acrylic ester, acrylonitrile			
Sterilisation	Non-sterile			
Issue Date	29 th Jul 2024	Version No	R03	

Intended use	A non-sterile head covering designed as a cap intended to 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
UN91220	Blue	A	Bottom Width	50 (±2)	100	600
		B	Top Length	13 (±1)		
		C	Cap Top Width	25 (±1)		
		D	Cap Top Length	1.5 (±1)		
UN91221	Green	A	Bottom Width	50 (±2)	100	600
		B	Top Length	13 (±1)		
		C	Cap Top Width	25 (±1)		
		D	Cap Top Length	1.5 (±1)		
UN91223	White	A	Bottom Width	50 (±2)	100	600
		B	Top Length	13 (±1)		
		C	Cap Top Width	25 (±1)		
		D	Cap Top Length	1.5 (±1)		
UN91224	Yellow	A	Bottom Width	50 (±2)	100	600
		B	Top Length	13 (±1)		
		C	Cap Top Width	25 (±1)		
		D	Cap Top Length	1.5 (±1)		

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)		

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

Storage conditions	Store in a cool dry place. Keep away from heat and direct sunlight.
Shelf life	3 years from the date of manufacture with the recommended storage conditions
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, Lot, Manufacturing & Expiry date, EC-REP, Manufacturer name and address
Additional information	The 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 563	Ashley Miller
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong
R03	29/07/2024	Update specification	Jack Wong

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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