

Product Specifications Sheet

Specification Sheet No	SSN-FT1358-003		
Product Name	Surgical Drapes		
Product Description	C-Section Drape (Teardrop Fenestration)		
Range	365 Healthcare		
Manufacturer	Sino Protection (Hefei) Medical Products Co., Ltd		
Material	5 SPI TB 3layers material, SPI TB material, SM PAD, 0.1mm clear PE		
Sterilisation	EO Sterile		
Issue Date	8th May 2024	Version No	R01a

Technical drawing of a C-Section Drape (Teardrop Fenestration) showing dimensions:

- Top width: 257 cm
- Total height: 325 cm
- Bottom width: 196 cm
- Top flap: 40 cm
- Side flaps: 40 cm
- Side flap: 18 cm
- Side flap: 22 cm
- Fenestration: 40 cm

Intended use	To be used to drape the patient to isolate a site from other areas of the patient's body or to contribute to reducing the risk of cross contamination.
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Packaging					
Product code	Colour	Dimension (cm)	Ply	Items per Pack	Qty – Shipper Carton
84-002365	Blue	257/196 x 325 (±2) (Fenestration 40 x 40)	3	1	5

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	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	5 years if stored as recommended		
Contraindications/Warnings	None		
Markings	365 Healthcare, Ref, Product name in 11 languages, Dimension, Images, Quantity Barcodes, Lot, Manufacture date, Expiry date, CE Mark, Single use, Latex free, Medical device, EO Sterile, Do not use if package is damaged, keep dry, keep away from sunlight, EC-REP, Manufacturer Name & Address, Distributor Name & Address		
Additional information	This product is latex free.		
Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.			

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

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
R01a	08/05/2024	Update to Mediq Healthcare UK brand replacing DSN846	Elizabeth Ogunkolade

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