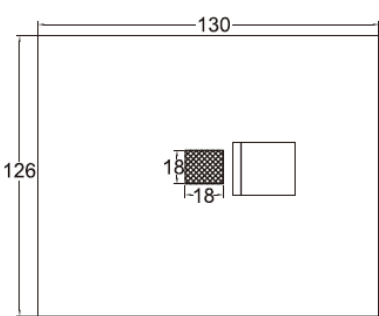


Product Specifications Sheet

Specification Sheet No	SSN-FT1358-014		
Product Name	Surgical Drapes		
Product Description	Cataract Drape 126cm x 130cm Incise Area 18 x 18cm		
Range	365 Healthcare		
Manufacturer	Sino Protection (Hefei) Medical Products Co., Ltd		
Material	Clear PE, Incise film		
Sterilisation	EO Sterile		
Issue Date	18 th June 2025	Version No	R01



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)	Items per Pack	Items per Inner	Qty – Shipper Carton
87-003365	Blue	126 x 130 (±2) (Incise 18 x 18)	1	50	100

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	1
Conformity Route	Medical Devices Directive 93/42/EEC		
Storage conditions	Store in a cool dry place away from heat and direct sunlight		
Shelf life	5 years if stored as recommended		
Contraindications/Warnings	No Known		
Markings	365 Healthcare, Ref, 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, Importer Name & Address, FSC and Recycle symbol for package.		
Additional information	This product is 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.

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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

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	18/06/2025	1 st version	Jack Wong

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