

Product Specifications Sheet

Specification Sheet No	SSN-FT1580-018		
Product Name	Surgical Drape		
Product Description	Patient Safety Beach Chair Shoulder Drape		
Range	365 Healthcare		
Manufacturer	Xuchang Zhengde Environstar Medical Products Co.,Ltd.		
Material	Blue SMS, co-extruded material, Transparent PEVA		
Sterilisation	EO Sterile		
Issue Date	11 th June 2024	Version No	R02

The diagram illustrates the layout of the Surgical Drape. It features a central 'Main Drape B' (406 x 260 cm) flanked by 'Cutting material' on both sides. Below 'Main Drape B' is 'Main Drape A' (406 x 260 cm). The overall dimensions are 124 cm (left), 158 cm (top), 124 cm (right), and 260 cm (left side). A central opening is marked with a dashed line and a dimension of 35 (±2) cm. A 'WRAPPER 100 x 100cm' is shown at the bottom right, with dimensions 100 cm (width) and 100 cm (height).

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	Items	Dimension (cm)	Items Per Packs	Qty – Inner	Qty – Shipper Carton
82-023365	Transparent	Drape	406 x 260 (±4)	1	6	12
	Blue	Wrapper	100 x 100			

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	1
Conformity Route	Medical Devices Directive (MDD 93/42/EEC) 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, Manufacturer Name & Address, EC-REP		
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	Jack Wong	Racheal Begg	R02	03 rd April 2024

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	10/06/2024	1 st version	Jack Wong
R02	11/06/2024	Update with new Mediq address	Jack Wong

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