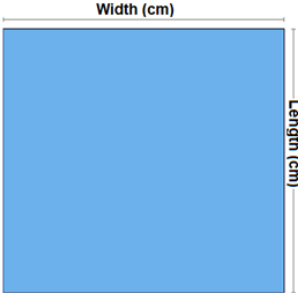


Product Specifications Sheet

Specification Sheet No	SSS-FT1580-005			
Product Name	Surgical Drapes			
Product Description	Utility Drape			
Range	365 Healthcare			
Manufacturer	Xuchang Zhengde Environstar Medical Products Co., Ltd.			
Material	Coextruded material, Blue hydrophilic SPP, Coextruded material (Blue hydrophilic SPP + PE + white waterproof SPP), Coextruded material			
Sterilisation	EO Sterile			
Issue Date	17 th June 2025	Version No	R03	

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) (width x Length)	Ply	Items per Pack	Qty – Inner Box	Qty – Shipper Carton
89-011365	Blue	50 x 60	/	1	32	128
89-012365		75 x 90	/		35	70
89-014365		75 x 45	3		47	94
89-015365		75 x 90	3		28	56

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	1
Conformity Route	Medical Device Regulation (EU) 2017/745		
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, 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		
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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Registered in England No. 62537

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	12/03/2024	Update to Mediq Healthcare UK brand replacing DSN844	Jack Wong
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong
R03	17/06/2025	Update Conformity Route with MDR	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