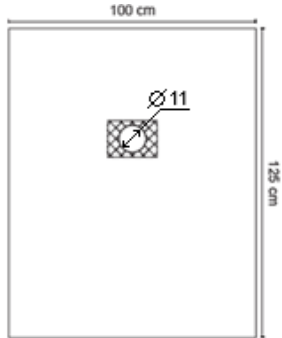


# Product Specifications Sheet

Specification Sheet No	SSS-FT1580-033			
Product Name	Surgical Drapes			
Product Description	Adhesive Aperture Drapes			
Range	365 Healthcare			
Manufacturer	Xuchang Zhengde Environstar Medical Products Co.,Ltd.			
Material	Co-extruded material, SPP hydrophilic, PE cast film			
Sterilisation	EO Sterile			
Issue Date	22 <sup>nd</sup> August 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	Qty- Inner	Qty – Shipper Carton
89-027365	Blue	100 x 125 (Hole Circular 11)	1	20	40

Quality Certification	ISO 13485:2016				
Device Classification	Class Is	Rule	1		
Conformity Route	Medical Devices 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	None				
Markings	365 Healthcare, Ref, Product name in 23 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				
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 <sup>rd</sup> 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	22/08/2025	1 <sup>st</sup> version	Jack Wong

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