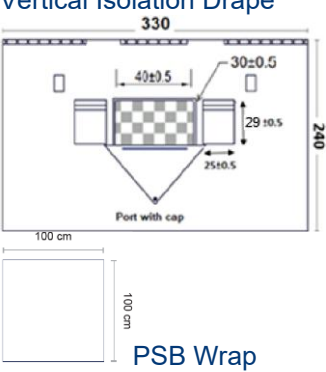


# Product Specifications Sheet

<b>Specification Sheet No</b>	SSN-FT1580-025			<b>Vertical Isolation Drape</b> 
<b>Product Name</b>	Surgical Drapes			
<b>Product Description</b>	DHS Vertical Isolation Drape			
<b>Range</b>	365 Healthcare			
<b>Manufacturer</b>	Xuchang Zhengde Environstar Medical Products Co.,Ltd.			
<b>Material</b>	Vertical Isolation Drape - PEVA antistatic, Incise film, PE PSB Wrap - PE antistatic			
<b>Sterilisation</b>	EO Sterile			
<b>Issue Date</b>	24 <sup>th</sup> July 2025	<b>Version No</b>	R02	

<b>Intended use</b>	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	Items	Description	Colour	Dimension (cm)	Items Per Pack	Qty- Inner	Qty – Shipper Carton
82-007365	Vertical Isolation Drape	Isolation Drape	Transparent	240 x 330(±2)	1	14	28
		Fluid Collection pouch	Transparent	54 x 49 (±1)	1		
		Fluid Collection pouch	Transparent	25 x 29 (±0.5)	2		
		Incise Film Area	Transparent	40 x 30 (±0.5)	1		
	PSB Wrap	Sterile Field Wrap	Blue	100 x 100	1		

<b>Quality Certification</b>	ISO 13485:2016		
<b>Device Classification</b>	Class Is	<b>Rule</b>	1
<b>Conformity Route</b>	Medical Devices Directives (EU) MDD 93/42/EEC		
<b>Storage conditions</b>	Store in a cool dry place away from heat and direct sunlight		
<b>Shelf life</b>	5 Years if stored as recommended		
<b>Contraindications/Warnings</b>	No Known		
<b>Markings</b>	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		
<b>Additional information</b>	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.

365 Healthcare	Mediq House
T: +44 (0) 1332 413 700	Arundel Avenue, Castle Donington
W: <a href="https://mediq.co.uk/">https://mediq.co.uk/</a>	Derby, DE74 2HJ

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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	30/05/2025	1 <sup>st</sup> version	Jack Wong
R02	24/07/2025	Update with 2 <sup>nd</sup> Fluid collection pouch dimension	Jack Wong

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