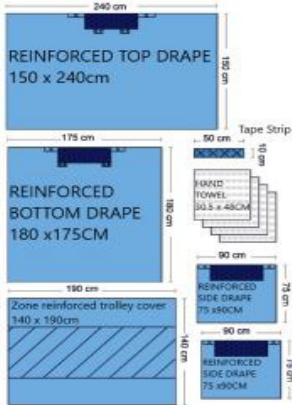


# Product Specifications Sheet

Specification Sheet No	SSN-FT1580-017			
Product Name	Surgical Drapes			
Product Description	Universal set 2 with Reinforced Drapes			
Range	365 Healthcare			
Manufacturer	Xuchang Zhengde Environstar Medical Products Co.,Ltd.			
Material	Coextruded material (hydrophilic SPP + PE + white waterproof SPP) Blue hydrophilic SS			
Sterilisation	EO Sterile			
Issue Date	11 <sup>th</sup> June 2024	Version No	R02	

Intended use	To be used to drape the patient to isolate a site from other areas of the patient's body or contribute to reducing the risk of cross contamination.
--------------	---

Packaging						
Product code	Colour	Item	Dimension (cm)	Items Per Pack	Qty- Inner	Qty – Shipper Carton
81-002365	Blue	Top Drape (x1)	150 x 240	1	6	12
		Bottom Drape (x1)	180 x 175			
		Side Drape (x2)	75 x 90			
		Trolley Cover (x1)	140 x 190			
		Tape strip (x1)	30.5 x 48			
	White	Hand towels (x4)	10 x 50			

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 2002/618, 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, EC-REP, Manufacturer Name & Address		
Additional information	Product is latex free		

Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.

Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004-02	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 <sup>rd</sup> April 2024



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

365 Healthcare is a trading division of Mediq Healthcare UK Ltd  
Registered in England No. 62537

### 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 <sup>st</sup> version	Jack Wong
R02	11/06/2024	Update with Mediq new address	Jack Wong

This document is uncontrolled when printed. The master document is controlled electronically, and document users are responsible for ensuring printed copies are valid prior to use to ensure it represents current practice within Mediq UK Ltd.

Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004-02	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 <sup>rd</sup> April 2024