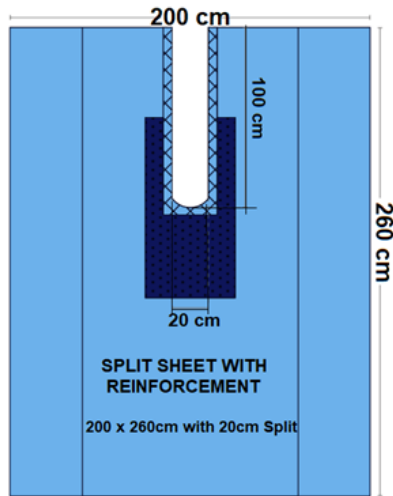


Product Specifications Sheet

Specification Sheet No	SSN-FT1580-015		
Product Name	Surgical Drapes		
Product Description	Split sheet with Reinforcement		
Range	365 Healthcare		
Manufacturer	Xuchang Zhengde Environstar Medical Products Co., Ltd.		
Material	Co-extruded material (blue SPP hydrophilic nonwoven + PE cast film + waterproof non-woven), Blue hydrophilic SS, co-extruded material (PE + waterproof SPP)		
Sterilisation	EO Sterile		
Issue Date	08 th June 2024	Version No	R02



The diagram illustrates the dimensions and structure of the surgical drape. It is a rectangular sheet measuring 200 cm in width and 260 cm in height. A central vertical split, 20 cm wide, runs through the middle. The split is reinforced with a blue material, while the rest of the sheet is a lighter blue. The text 'SPLIT SHEET WITH REINFORCEMENT' and '200 x 260cm with 20cm Split' is printed on the sheet.

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
89-032365	Blue	200 x 260 (Split 20 x 100)	1	13	26

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.			

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

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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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	07/06/2024	Update to Mediq Healthcare UK brand replacing DSN101	Jack Wong
R02	08/06/2024	Update Mediq Healthcare UK address	Jack Wong

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