

Product Specifications Sheet

Specification Sheet No	SSN-FT1580-034		
Product Name	Equipment cover		
Product Description	Band Bag		
Range	365 Healthcare		
Manufacturer	Xuchang Zhengde Environstar Medical Products Co., Ltd.		
Material	PE film with blue elastic		
Sterilisation	EO Sterile		
Issue Date	21 st October 2025	Version No	R01



Intended use	A single use device intended to be used as a barrier, isolating any potential contamination sources coming from hospital equipment.
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Product code	Colour	Diameter (cm)	Qty – Shipper Carton
16-1170365	Transparent	70	40pcs
16-1190365		90	44pcs
16-1140365		140	24pcs

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	1
Conformity Route	Medical Devices Directive (EU) 94/72/EEC		
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, Code, Quantity, Product name, Barcodes, Lot, Image, Manufacturing & 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 and address		
Additional information	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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DMS 04-004-02	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 rd April 2024
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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	21/10/2025	1 st version	Jack Wong

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