

Product Procedure Specifications Sheet

Specification Sheet No	SSN-FT1390-010		
Product Name	Vaginal Exam Pack		
Product Code	36513506 (REV 5)		
Range	365 Healthcare		
Manufacturer	Wujiang Kangxin Surgical Dressings Co. Ltd		
Packaging	120pcs		
Sterilisation	EO Sterile		
Issue Date	04 th Oct 2024	Version No	R01

Intended use	Intended to provide the supporting items required for gynaecology procedures and surgery
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Pack content				
Item	Product code	Quantity	Dimensions	Material
White 2 Part Tray Ps	3603	1	18 x 9.8 x 2.5cm	Polystyrene
White Dressing Towel	4001	3	38 x 40cm	Paper
White Non-Woven Ball with XRD Medium	9602	5	17 x 17cm	70% Viscose, 30% Terylene, XRD Thread
Blue Tissue Backed Drape	3303	1	60 x 60cm	PE Film and Absorbent Tissue

Quality Certification	ISO 13485:2016		
Device Classification	Class IIa	Rule	Article 22
Conformity Route	Medical Devices Regulation (EU) 2017/745 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 - under recommended storage conditions		
Contraindications/Warnings	None		
Markings	Product Name, REF, 365 Logo and Address, Lot Number, Manufacturing Date, Expiry Date, Medical Device, Single Use, EO Sterile, Single sterile barrier, do not use if package damaged, Keep dry and away from sunlight, CE, ECREP, Manufacturer		
Additional information	Products are Latex and phthalate free Products contain no hazardous substances Products contain no medicinal substances		

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 04-004-03	Procedure Pack 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	04/10/2024	1 st version	Jack Wong

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