

Product Procedure Specifications Sheet

Specification Sheet No	SSN-FT1390-012		
Product Name	Vaginal Examination Pack		
Product Code	36513050		
Range	365 Healthcare		
Manufacturer	Wujiang Kangxin Surgical Dressings Co. Ltd		
Packaging	120pcs/case		
Sterilisation	EO Sterile		
Issue Date	04 th Oct 2024	Version No	R01



Intended use	Intended to provide the supporting items required for ophthalmic cataract procedures and surgery
--------------	--

Pack content				
Item	Product code	Quantity	Dimensions	Material
White 2 Part Tray	3603	1	18x9.8x2.5cm	Polystyrene
White Dressing Towel	4001	2	38x40cm	Paper
White Non Woven Ball With XRD	9602	5	17x17cm	Viscose & Terylene, XRD Thread
Blue Tissue Backed Drape	3303	1	60x60cm	Pe Film And Absorbent Tissue
Blue Padded Drape	10601	1	50x50cm	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.

365 Healthcare	Mediq House
T: +44 (0) 1332 413 700	Arundel Avenue, Castle Donington
W: https://mediq.co.uk/	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	04/10/2024	1 st version	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 Healthcare UK Ltd.

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