

## Product Procedure Specifications Sheet

<b>Specification Sheet No</b>	SSN-FT1390-020			
<b>Product Name</b>	Renal Packs			
<b>Product Description</b>	CVC on/off pack			
<b>Range</b>	365 Healthcare			
<b>Manufacturer</b>	Wujiang Kangxin Surgical Dressings Co., Ltd.			
<b>Packaging</b>	36514271 (REV 2) 90pcs/case			
<b>Sterilisation</b>	EO Sterile			
<b>Issue Date</b>	21st May 2024	<b>Version No</b>	R03	

<b>Intended use</b>	Intended to act as an accessory pack for the placement of renal patients on and off haemodialysis machines for the purpose of renal dialysis
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Pack content				
Item	Product code	Quantity	Dimensions	Material
<b>On Pack</b>				
Non Woven Swabs	3103	5	10 x 10cm	Viscose & Terylene
Nitrile Gloves	4611	1 pair	Palm 9.5cm	Nitrile
Luer Lock syringe	10411	2	5ml	Piston Plug – Synthetic rubber Core bar and sheath – Polypropylene Lubricant – medical silicone oil Adhesive – Epoxy resin
Tissue Backed Drape	8702	1	50 x 50cm	PE Film and absorbent tissue
Yellow Bag	2001	1	35 x 45cm	High-density polyethylene
Tissue Backed Sterile Field	8802	1	50 x 50cm	Pulp Tissue+PE Film Lamination
<b>Off Pack</b>				
Non Woven Swabs	3103	5	10 x 10cm	Viscose & Terylene
Nitrile Gloves	4611	1 pair	Palm 9.5cm	Nitrile
Luerlock Syringes	10409	2	3ml	Piston Plug – Synthetic rubber Core bar and sheath – Polypropylene Lubricant – medical silicone oil Adhesive – Epoxy resin
Luerlock Syringes	10410	2	10ml	
Tissue Backed Drape	8702	1	50 x 50cm	PE Film and absorbent tissue
Deadenders/End Caps - Red	6301	2	1.9cm	Polyethylene
Yellow Bag	2001	1	35 x 45cm	High-density polyethylene
Green Needle Safety 21g	5001	2	21G, 38-2.5+1.5	Needle – Stainless Steel Needle hub & protective cap – Medical grade polypropylene
Tissue Backed Sterile Field	8802	1	50 x 50cm	Pulp Tissue+PE Film Lamination

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 <sup>rd</sup> April 2024

<b>Quality Certification</b>	ISO 13485		
<b>Device Classification</b>	Class IIa	<b>Rule</b>	Article 22
<b>Conformity Route</b>	Medical Devices Regulation (EU) 2017/745		
<b>Storage conditions</b>	Store in a cool dry place away from heat and direct sunlight.		
<b>Shelf life</b>	3 years if stored under recommended storage conditions		
<b>Contraindications/Warnings</b>	No known		
<b>Markings</b>	Product Name, REF, 365 Logo and Address, Lot Number, Manufacturing Date, Expiry Date, Medical Device, Single Use, EO Sterile, Single sterile barrier, Latex free, do not use if package damaged, Keep dry and away from sunlight, CE, ECREP, Manufacturer		
<b>Additional information</b>	Products are Latex and phthalate free. Products contain no hazardous substances. Products contain no medical substances.		
<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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## 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	29/01/2026	Update Mediq Healthcare UK address	Jack Wong
R02	30/01/2026	Correct the case qty	Jack Wong

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