

Product Procedure Specifications Sheet

Specification Sheet No	SSN-FT1357-004		
Product Name	365-12032		
Product Description	Anaesthetic Pack		
Range	365 Healthcare		
Manufacturer	Shanghai ISO Medical Products Co Ltd (SIMP)		
Packaging	60pcs		
Sterilisation	EO Sterilisation		
Issue Date	02 nd May 2024	Version No	R01



Intended use	Surgical Dressing Kit is intended for the out-patient service clinical use and operation wound treatment.
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Pack content				
Item	Product code	Quantity	Dimensions	Material
Bowl	01.03.00.0043	1	250ml	Polypropylene
3 Part Tray	01.03.00.0037	1	198x135x38mm	Polystyrene
Sponge Sticks Blue	01.00.00.0109	2	N/A	Polyurethane foam, PS
XRD Green Swab	03.01.00.0204	1 Bundle of 5 Tied	10x10cm 12ply	Cotton yarn with XRD thread
Towel	03.08.00.0022	2	40x43cm 2ply	Pulp
Clear Fenestrated Drape with adhesive edge	03.08.00.0290	1	75X95CM	Polyethylene / Plastic
Tissue Backed Drape	03.08.00.0185	1	90x75cm	Polyethylene / Plastic
Tissue Backed Sterile Field	01.08.00.0300	1	90x75cm	Polyethylene / Plastic

Quality Certification	ISO 13485		
Device Classification	Ila	Rule	N/A
Conformity Route	Medical Devices Directive (93/42/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 contraindication		
Markings	365 Healthcare, Ref, Product name, Lot Number, Quantity, Data Matrix, EC-REP, EO Sterile, Manufacturing date, Expiry date, CE Mark, Single use, Latex free, Medical device, Do not use if package is damaged, keep dry, keep away from sunlight, Manufacturer Name & Address		
Additional information	Latex free and sterile. Do not use if the packaging is broken.		

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	Ashley Miller	Racheal Begg	R01	12 th June 2023



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	02/05/2024	Update to Mediq UK Brand	Jack Wong

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