

Product Procedure Specifications Sheet

Specification Sheet No	SSN-FT1357-006			
Product Name	365-12650			
Product Description	Anaesthetic Pack			
Range	365 Healthcare			
Manufacturer	Shanghai ISO Medical Products Co Ltd (SIMP)			
Packaging	50pcs			
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 (Approx.)	Material
Sterile Field	01.08.00.0277	2	90 x 90cm	PE + Paper
3 Part tray	01.03.00.0044	1	18.2 x 9.8 x 2.5cm	PS
Gauze swabs 12 ply	03.01.00.0194	5	Folded size: 10 x 10xm	Cotton
Cup	01.03.00.0012	1	60ml	PP
Sponge Sticks	01.00.00.0109	3	15cm	PS stick + Polyurethane foam
Drape	03.08.00.0145	1	Unfolded size: 75 x 90cm	PE

Quality Certification	ISO 13485		
Device Classification	Is	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.			

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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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



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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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