


Product Specifications Sheet

Specification Sheet No	SSN-JAL007-004			
Product Name	X-ray Detectable Gauze Swabs			
Product Description	XRD Gauze Products			
Range	Premier			
Manufacturer	Allmed Medical Products Co., Ltd			
Material	100% Cotton Gauze with $\geq 60\%$ Barium Sulphate X-Ray Detectable Thread			
Sterilisation	EO Sterile			
Issue Date	15 th August 2025	Version No	R02a	

Intended use	Invasive device for transient>short term use during surgery. To be used for absorbing fluids and packing wounds and/or cavities.
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Packaging									
Product code	Colour	Dimension (cm)	Stitched Edge	Taped	Ply	Tied	Items Per Pack	Qty- Inner	Qty – Shipper Carton
0101	White	5x5			32	Tied 5's	2 boxes	80	160
0101S	White	5x5			32	Tied 5 x 2	9 PE bags	20	180
0102	Green	7.5x7.5			8	Tied 5's	2 boxes	80	160
0103	White	7.5x7.5			12	Tied 5's	2 boxes	80	160
0104S	White	10x7.5	✓		32	Tied 5's	2 boxes	80	160
0104A	White	10x7.5			32	Tied 5's	8 PE bags	15	120
0106	White	10x10			12	Tied 5's	2 boxes	70	140
0107A	White	10x10			16	Tied 5's	8 PE bags	20	160
0110A	White	10x10			32	Tied 5's	8 PE bags	15	120
0110S	White	10x10			32	Tied 5 x 2	8 PE bags	10	80
0113A	White	15x2.5	✓		16	Tied 5's	5 boxes	80	400
0116A	White	15x10			24	Tied 5's	6 PE bags	15	90
0116S	White	15x10			24	Tied 5 x 2	6 PE bags	10	60
0122A	White	36x11			16	Tied 5's	4 boxes	15	60
0130A	White	22.5x22.5	✓	✓	12	Tied 5's	8 PE bags	10	80
0133A	White	30x30	✓	✓	12	Tied 5's	4 PE bags	10	40
0136A	White	30x30	✓	✓	24	Tied 5's	4 PE bags	6	24
0142A	White	45x45	✓	✓	12	Tied 5's	3 PE bags	8	24
0150	Green	10x10			12	Tied 5's	2 boxes	70	140
0160	White	22.5x22.5	✓		12	Tied 5's	2 boxes	24	48
0165	White	30x30			12	Tied 5's	2 boxes	14	28
0166A	White	30x30	✓		12	Tied 5's	4 PE bags	10	40
0170	White	45x45	✓		12	Tied 5's	2 boxes	6	12

Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 rd April 2024

Quality Certification	ISO 13485:2016		
Device Classification	Class IIa	Rule	7
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 – If stored as recommended above		
Contraindications/Warnings	None		
Markings	Premier Logo, Ref, Quantity, Product Name, Dimension, Colour, Ply, Double Wrapped, Tied/Pack, BP Type 13 Light, CE Mark, Latex Free, Single Use, Medical Device, EO Sterile, Do Not Use If Package Is Damaged, Keep Dry Keep Away From Sunlight, Lot, Barcodes, Manufacturing Date, Expiry Date, EC-REP, Distributor name and address, Importer name and address		
Additional information	Latex free. Each pack contains 3 batch number traceability stickers. X-Ray detectable swabs should not be cut, altered or opened out as this will expose raw edges of the gauze and may cause the X-Ray detectable line to be exposed on the surface of the gauze.		
<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
R01a	16/09/2024	Update to Mediq Healthcare UK brand replacing DSN001	Elizabeth Ogunkolade
R02a	15/08/2025	Update to revision 2	Elizabeth Ogunkolade

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