

## Product Specifications Sheet

|                        |                                                                                                                                   |            |      |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------|------------|------|
| Specification Sheet No | SSN-JAL007-002                                                                                                                    |            |      |
| Product Name           | XRD Gauze Swab                                                                                                                    |            |      |
| Product Description    | XRD Gauze Swab                                                                                                                    |            |      |
| Range                  | Premier                                                                                                                           |            |      |
| Manufacturer           | Allmed Medical Products Co., Ltd                                                                                                  |            |      |
| Material               | 100% Cotton Gauze: Type 13 Light, Warp threads, Weft threads, minimum mass X-Ray Detectable PVC Fibre Thread ≥60% Barium Sulphate |            |      |
| Sterilisation          | Non-sterile                                                                                                                       |            |      |
| Issue Date             | 15 <sup>th</sup> May 2024                                                                                                         | Version No | R01a |



|              |                                                                                                                  |
|--------------|------------------------------------------------------------------------------------------------------------------|
| Intended use | Intended to be used for transient use on surgical incision to control bleeding, absorb fluid during a procedure. |
|--------------|------------------------------------------------------------------------------------------------------------------|

| Packaging    |        |                                    |     |                |            |                      |
|--------------|--------|------------------------------------|-----|----------------|------------|----------------------|
| Product code | Colour | Dimension (cm)                     | Ply | Items Per Pack | Qty- Inner | Qty – Shipper Carton |
| 7012A        | Green  | 7.5x7.5cm                          | 8   | T5's           | 60x20      | 1200                 |
| 7013A        | Green  | 10x7.5cm                           | 32  | T5's           | 40x10      | 400                  |
| 7156         | Green  | 10x10cm                            | 12  | T5's           | 24x20      | 480                  |
| 7156A        | Green  | 10x10cm                            | 12  | T5's           | 40x20      | 800                  |
| 7104         | White  | 7.5x7.5cm                          | 12  | T5's           | 10x100     | 1000                 |
| 7107A        | White  | 10x7.5cm                           | 32  | T5's           | 40x10      | 400                  |
| 7109         | White  | 10x10cm                            | 12  | T5's           | 50x20      | 1000                 |
| 7110         | White  | 10x10cm                            | 16  | T5's           | 24x20      | 480                  |
| 7113         | White  | 10x10cm                            | 32  | T5's           | 12x20      | 240                  |
| 7116         | White  | 15x2.5cm (Stitched Edge)           | 16  | T5's           | 12x20      | 240                  |
| 7119         | White  | 15x10cm                            | 24  | T5's           | 12x20      | 240                  |
| 7122         | White  | 25x2.5cm (Stitched Edge)           | 16  | T5's           | 12x20      | 240                  |
| 7130         | White  | 22.5x22.5cm (Taped, Stitched Edge) | 12  | T5's           | 8x20       | 160                  |
| 7133         | White  | 30x30cm (Taped, Stitched Edge)     | 12  | T5's           | 8x10       | 80                   |
| 7136         | White  | 30x30cm (Taped)                    | 24  | T5's           | 4x10       | 40                   |
| 7139         | White  | 45x45cm (Taped)                    | 6   | T5's           | 12x10      | 120                  |
| 7142         | White  | 45x45cm (Taped)                    | 12  | T5's           | 4X10       | 40                   |

| Document Reference | Document Name               | Reviewed By   | Approved By  | Revision Number | Issue Date                 |
|--------------------|-----------------------------|---------------|--------------|-----------------|----------------------------|
| DMS 04-004         | Product Specification Sheet | Ashley Miller | Racheal Begg | R01             | 12 <sup>th</sup> June 2023 |

|                                                                                                                   |                                                                                                                                                                                                             |      |   |
|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---|
| Quality Certification                                                                                             | ISO 13485                                                                                                                                                                                                   |      |   |
| Device Classification                                                                                             | Ila                                                                                                                                                                                                         | Rule | 7 |
| Conformity Route                                                                                                  | Medical Devices Directive (MDD 93/42/EEC)                                                                                                                                                                   |      |   |
| Storage conditions                                                                                                | Store in a cool dry place away from heat and sunlight                                                                                                                                                       |      |   |
| Shelf life                                                                                                        | 5 Years if stored as recommended above                                                                                                                                                                      |      |   |
| Contraindications/Warnings                                                                                        | None                                                                                                                                                                                                        |      |   |
| Markings                                                                                                          | Premier Logo, Size, Quantity, Code Ref, Lot No, Expiry Date, CE Marking, Latex free Symbol, Non-Sterile Symbol, Manufacturer name and address, Distributor name and address                                 |      |   |
| Additional information                                                                                            | Latex free<br>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. |      |   |
| 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.

|                                                            |                                  |
|------------------------------------------------------------|----------------------------------|
| 365 Healthcare                                             | Mediq House                      |
| T: +44 (0) 1332 413 700                                    | Arundel Avenue, Castle Donington |
| W: <a href="https://mediq.co.uk/">https://mediq.co.uk/</a> | Derby, DE74 2HJ                  |

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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            | 15/05/2024    | Update to Mediq UK Brand replacing DSN 839 | Elizabeth Ogunkolade |
|                 |               |                                            |                      |
|                 |               |                                            |                      |

| Document Reference | Document Name               | Reviewed By   | Approved By  | Revision Number | Issue Date                 |
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| DMS 04-004         | Product Specification Sheet | Ashley Miller | Racheal Begg | R01             | 12 <sup>th</sup> June 2023 |



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|--------------------|-----------------------------|---------------|--------------|-----------------|----------------------------|
| DMS 04-004         | Product Specification Sheet | Ashley Miller | Racheal Begg | R01             | 12 <sup>th</sup> June 2023 |