

## Product Specifications Sheet

|                        |                                  |            |      |                                                                                     |
|------------------------|----------------------------------|------------|------|-------------------------------------------------------------------------------------|
| Specification Sheet No | SSN-JAL007-006                   |            |      |  |
| Product Name           | Tipped Applicator                |            |      |                                                                                     |
| Product Description    | Cotton Tipped Applicator/Swab    |            |      |                                                                                     |
| Range                  | Universal                        |            |      |                                                                                     |
| Manufacturer           | Allmed Medical Products Co., Ltd |            |      |                                                                                     |
| Material               | Wooden stick<br>Cotton Tip       |            |      |                                                                                     |
| Sterilisation          | EO Sterile                       |            |      |                                                                                     |
| Issue Date             | 26th September 2024              | Version No | R01a |                                                                                     |

|              |                                                         |
|--------------|---------------------------------------------------------|
| Intended use | For general use in medical preparation and examinations |
|--------------|---------------------------------------------------------|

### Packaging

| Product code | Colour  | Dimension (cm) | Items Per Pack | Qty- Inner               | Qty – Shipper Carton |
|--------------|---------|----------------|----------------|--------------------------|----------------------|
| UN982S       | Natural | Approx. 15cm   | 5pcs           | 500pcs<br>100 packs of 5 | 5000pcs<br>(10x500)  |

|                                                                                                                   |                                                                                                                                                                                                                                                                                                    |      |   |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---|
| Quality Certification                                                                                             | ISO 13485:2016                                                                                                                                                                                                                                                                                     |      |   |
| Device Classification                                                                                             | Class Is                                                                                                                                                                                                                                                                                           | Rule | 5 |
| Conformity Route                                                                                                  | Medical Device 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 above                                                                                                                                                                                                                                                             |      |   |
| Contraindications/Warnings                                                                                        | Not recommended for use in the ear canal                                                                                                                                                                                                                                                           |      |   |
| Markings                                                                                                          | Product name, Universal Logo, Code Ref, latex free, expiry date, lot number, single use symbols, CE mark, EO Sterile, Do not resterilise, 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 |      |   |
| Additional information                                                                                            | The product is latex free and sterile                                                                                                                                                                                                                                                              |      |   |
| 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         | Product Specification Sheet | Jack Wong   | Racheal Begg | R02             | 03 <sup>rd</sup> April 2024 |

## 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            | 26/09/2024    | Update to Mediq Healthcare UK brand replacing DSN837 | Elizabeth Ogunkolade |
|                 |               |                                                      |                      |
|                 |               |                                                      |                      |

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