

## Product Specifications Sheet

|                        |                                               |            |     |                                                                                     |
|------------------------|-----------------------------------------------|------------|-----|-------------------------------------------------------------------------------------|
| Specification Sheet No | SSN-TAPES(NS)-004                             |            |     |  |
| Product Name           | Medical tape                                  |            |     |                                                                                     |
| Product Description    | Silkpore Medical Tape                         |            |     |                                                                                     |
| Range                  | Premier                                       |            |     |                                                                                     |
| Manufacturer           | Mediq Healthcare UK Ltd                       |            |     |                                                                                     |
| Material               | Cellulose acetate substrate, Acrylic adhesive |            |     |                                                                                     |
| Sterilisation          | Non-sterile                                   |            |     |                                                                                     |
| Issue Date             | 21st May 2024                                 | Version No | R02 |                                                                                     |

|                     |                                                                                                                                                                                                                            |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Intended use</b> | A long narrow flexible band of fabric coated on one or both sides with a pressure sensitive adhesive, intended to non-invasively adhere to the skin surface to fix a dressing in place, or attach objects (e.g. catheter). |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Packaging    |        |            |            |            |                      |
|--------------|--------|------------|------------|------------|----------------------|
| Product code | Colour | Width (cm) | Length (m) | Qty- Inner | Qty – Shipper Carton |
| 5076         | White  | 1.25±0.05  | 9.1±0.1    | 24         | 240                  |
| 5077         | White  | 2.5±0.1    | 9.1±0.1    | 12         | 120                  |
| 5078         | White  | 5.0±0.3    | 9.1±0.1    | 6          | 60                   |
| 5079         | White  | 7.5±0.3    | 9.1±0.1    | 4          | 40                   |

|                                                                                                                   |                                                                                                                                                                                                                                                                  |      |   |
|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---|
| Quality Certification                                                                                             | ISO 13485                                                                                                                                                                                                                                                        |      |   |
| Device Classification                                                                                             | I                                                                                                                                                                                                                                                                | Rule | 1 |
| Conformity Route                                                                                                  | Medical Devices Regulation (EU) 2017/745<br>Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)                                                                                                                                          |      |   |
| Storage conditions                                                                                                | Store in a cool dry place. Keep away from heat and direct sunlight.                                                                                                                                                                                              |      |   |
| Shelf life                                                                                                        | 5 years from the date of manufacture with the recommended storage conditions                                                                                                                                                                                     |      |   |
| Contraindications/Warnings                                                                                        | None                                                                                                                                                                                                                                                             |      |   |
| Markings                                                                                                          | Premier logo, code ref, product name, dimension, quantity, colour, non-sterile, CE mark, single use, latex free, medical device, keep dry, keep away from sunlight, barcodes, manufacturing date, expiry date, lot number, manufacturer name and address, EC-REP |      |   |
| Additional information                                                                                            | The product is latex free, non-sterile and single use                                                                                                                                                                                                            |      |   |
| 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   |
|-----------------|---------------|--------------------------------------------|--------------|
| R01             | 03/07/2023    | Update to Mediq UK Brand replacing DSN 471 | Racheal Begg |
| R02             | 21/05/2024    | Update Mediq Healthcare UK address         | Jack Wong    |
|                 |               |                                            |              |
|                 |               |                                            |              |

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