

# Product Specifications Sheet

|                               |                            |                   |     |
|-------------------------------|----------------------------|-------------------|-----|
| <b>Specification Sheet No</b> | SSN-PPETF-OSH-001          |                   |     |
| <b>Product Name</b>           | Oversleeves                |                   |     |
| <b>Product Description</b>    | Premier Oversleeves        |                   |     |
| <b>Range</b>                  | Premier                    |                   |     |
| <b>Manufacturer</b>           | Mediq Healthcare UK Ltd.   |                   |     |
| <b>Material</b>               | Polyethene                 |                   |     |
| <b>Sterilisation</b>          | Non-Sterile                |                   |     |
| <b>Issue Date</b>             | 11 <sup>th</sup> June 2025 | <b>Version No</b> | R01 |



|                     |  |
|---------------------|--|
| <b>Intended use</b> | For use in areas requiring protection against mechanical action, the effect of which are superficial and light industrial. |
|---------------------|--|

| Packaging    |                                 |        |                                   |                  |                         |
|--------------|---------------------------------|--------|-----------------------------------|------------------|-------------------------|
| Product code | Dimension (± 1cm)<br>L x W (cm) | Colour | Thickness<br>(Approximately) (mm) | Qty -<br>Polybag | Qty – Shipper<br>Carton |
| 2939         | 40 x 20                         | White  | 0.02                              | 100              | 2000                    |
| 2944         | 40 x 20                         | Blue   |                                   |                  |                         |

|  |  |             |     |
|--|--|-------------|-----|
| <b>Quality Certification</b>   | ISO 13485  |             |     |
| <b>Device Classification</b>   | PPE Category I   | <b>Rule</b> | N/A |
| <b>Conformity Route</b>  | PPE Regulation (EU) 2016/425   |             |     |
| <b>Storage conditions</b>  | Store in a cool dry place away from heat and direct sunlight   |             |     |
| <b>Shelf life</b>  | 5 years if stored as recommended above   |             |     |
| <b>Contraindications/Warnings</b>  | No Known   |             |     |
| <b>Markings</b>  | Premier logo, Ref, Quantity, Product name, Colour, Size, Barcode, Lot, Manufacture date, Expiry date, CE Mark, UKCA, Medical device, Non-sterile, Single use, Latex free, keep dry, keep away from sunlight, Manufacturer name & Address, EC-REP |             |     |
| <b>Additional information</b>  | The product is latex free and non-sterile.   |             |     |
| <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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| 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             | 11/06/2025    | Update to Mediq UK Brand replacing DSN057 | Jack Wong  |
|                 |               |   |            |
|                 |               |   |            |

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| DMS 04-004         | Product Specification Sheet | Jack Wong   | Racheal Begg | R02             | 03 <sup>rd</sup> April 2024 |