

## Product Specifications Sheet

|                        |                            |            |     |                                                                                     |
|------------------------|----------------------------|------------|-----|-------------------------------------------------------------------------------------|
| Specification Sheet No | SSN-PPETF-GWNS-001         |            |     |  |
| Product Name           | Protective Thumb Loop Gown |            |     |                                                                                     |
| Product Description    | Protective Thumb Loop Gown |            |     |                                                                                     |
| Range                  | 365 Healthcare             |            |     |                                                                                     |
| Manufacturer           | Mediq Healthcare UK Ltd.   |            |     |                                                                                     |
| Material               | Polythene                  |            |     |                                                                                     |
| Sterilisation          | Non-sterile                |            |     |                                                                                     |
| Issue Date             | 21st May 2024              | Version No | R02 |                                                                                     |

|                     |                                                                           |
|---------------------|---------------------------------------------------------------------------|
| <b>Intended use</b> | To be used to protect the end user from low risk patient care activities. |
|---------------------|---------------------------------------------------------------------------|

| Packaging    |        |                         |                  |                       |                                |
|--------------|--------|-------------------------|------------------|-----------------------|--------------------------------|
| Product code | Colour | Sleeve Length (Approx.) | Length (Approx.) | Chest Width (Approx.) | Qty – Shipper Carton           |
| PM4-7194     | Blue   | 84cm                    | 110cm            | 84cm                  | 75pcs<br>(5 Inner boxes of 15) |

|                                                                                                                   |                                                                                                                                                                                                                                                                                                                                            |      |     |
|-------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-----|
| Quality Certification                                                                                             | ISO 13485                                                                                                                                                                                                                                                                                                                                  |      |     |
| Device Classification                                                                                             | PPE Category I (Protection from Minimal Risk)                                                                                                                                                                                                                                                                                              | Rule | N/A |
| Conformity Route                                                                                                  | (EU) 2016/425 Personal Protective Equipment.                                                                                                                                                                                                                                                                                               |      |     |
| 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                                                                                        | N/A                                                                                                                                                                                                                                                                                                                                        |      |     |
| Markings                                                                                                          | Product Description and Ref, CE Mark (Minimal Risk), UKCA Mark, Single Use, Latex free, Keep aways from rain and sunshine, Lot Number, Manufacture and Expiry Date                                                                                                                                                                         |      |     |
| Additional information                                                                                            | The product is latex free and non-sterile.<br>EN 14126:2003 Protective Clothing – Type PB 6 & 3<br>ISO 811:2018 Textiles, Determination of resistance to water penetration<br>ANSI/AAMI PB70:2012 -Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities ≤1.0g Level 3 |      |     |
| 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             | 06/22/2023    | Update to Mediq Healthcare UK brand replacing DSN | Jack Wong  |
| R02             | 21/05/2024    | Update Mediq Healthcare UK address                | Jack Wong  |
|                 |               |                                                   |            |
|                 |               |                                                   |            |

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