

# Product Specifications Sheet

|                        |                       |            |     |                                                                                     |
|------------------------|-----------------------|------------|-----|-------------------------------------------------------------------------------------|
| Specification Sheet No | SSN-FT1580-003        |            |     |  |
| Product Name           | Woundcare / Dressings |            |     |                                                                                     |
| Product Description    | Foam Dressing         |            |     |                                                                                     |
| Range                  | 365 Healthcare        |            |     |                                                                                     |
| Manufacturer           | Zhende Medical Co Ltd |            |     |                                                                                     |
| Material               | Polyurethane film     |            |     |                                                                                     |
| Sterilisation          | Gamma Irradiation (R) |            |     |                                                                                     |
| Issue Date             | 21st May 2024         | Version No | R02 |                                                                                     |

|              |                                                                                            |
|--------------|--------------------------------------------------------------------------------------------|
| Intended use | For use on wounds with low or moderate level of exudates, including post-operative wounds. |
|--------------|--------------------------------------------------------------------------------------------|

| Packaging    |                      |                     |                   |                            |             |                |                      |
|--------------|----------------------|---------------------|-------------------|----------------------------|-------------|----------------|----------------------|
| Product code | Colour               | Product Length (cm) | Product Width(cm) | Liquid Absorptive Capacity | Qty - Pouch | Qty – Per Pack | Qty – Shipper Carton |
| 36590060     | Skin colour or Beige | 5                   | 5                 | ≥50g/100cm <sup>2</sup>    | 1           | 10             | 200                  |
| 36590061     |                      | 7.5                 | 7.5               |                            |             |                |                      |
| 36590062     |                      | 10                  | 10                |                            |             |                |                      |
| 36590063     |                      | 15                  | 15                |                            |             |                |                      |
| 36590064     |                      | 20                  | 10                |                            |             |                |                      |
| 36590065     |                      | 20                  | 20                |                            |             |                |                      |

|                                                                                                                   |                                                                                                                                                                                                                                                                                                                               |      |   |
|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---|
| Quality Certification                                                                                             | ISO 13485                                                                                                                                                                                                                                                                                                                     |      |   |
| Device Classification                                                                                             | Class IIb                                                                                                                                                                                                                                                                                                                     | Rule | 4 |
| Conformity Route                                                                                                  | Medical Devices Directives (EU) MDD 93/42/EEC                                                                                                                                                                                                                                                                                 |      |   |
| Storage conditions                                                                                                | Store in a cool dry place away from heat and direct sunlight                                                                                                                                                                                                                                                                  |      |   |
| Shelf life                                                                                                        | 3 years if stored as recommended above                                                                                                                                                                                                                                                                                        |      |   |
| Contraindications/Warnings                                                                                        | Do not cut the dressing.                                                                                                                                                                                                                                                                                                      |      |   |
| Markings                                                                                                          | 365 logo, Ref, Quantity, Product name, Dimension, Barcode, Lot, Manufacture date, Expiry date, Instruction For Use, CE Mark, Medical device, Gamma Irradiation (R)-Sterile, Single use, Do not re-sterilize, Latex free, keep dry, keep away from sunlight, Manufacturer name & Address, Distributor name and address, EC-REP |      |   |
| Additional information                                                                                            | Absorptive capacity of the dressing is no less than eight times its own weight.<br>The dressings are waterproof (able to withstand a hydrostatic head of 500 mm water for 300s)<br>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           |
|-----------------|---------------|-------------------------------------------|----------------------|
| R01             | 14/12/2023    | Update to Mediq UK Brand replacing DSN614 | Elizabeth Ogunkolade |
| R02             | 21/05/2024    | Update Mediq Healthcare UK address        | Jack Wong            |
|                 |               |                                           |                      |
|                 |               |                                           |                      |

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