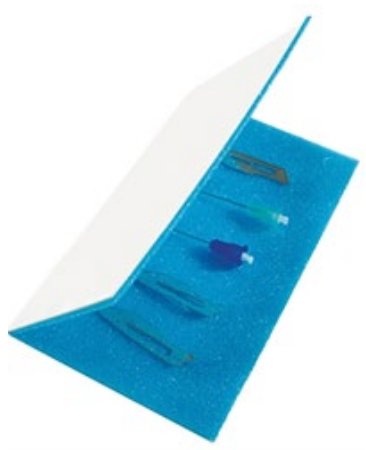


# Product Specifications Sheet

|                               |                                                                                                                                       |                   |     |                                                                                     |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------|-----|-------------------------------------------------------------------------------------|
| <b>Specification Sheet No</b> | SSN-TA023-001                                                                                                                         |                   |     |  |
| <b>Product Name</b>           | Misc / Supplementary Items                                                                                                            |                   |     |                                                                                     |
| <b>Product Description</b>    | Universal Sharps Protecta Pad                                                                                                         |                   |     |                                                                                     |
| <b>Range</b>                  | Universal                                                                                                                             |                   |     |                                                                                     |
| <b>Manufacturer</b>           | P3 Medical Ltd                                                                                                                        |                   |     |                                                                                     |
| <b>Material</b>               | Cardboard, hot melt adhesive, foam, double coated adhesive tape, polypropylene adhesive tape, siliconised release liner, polyurethane |                   |     |                                                                                     |
| <b>Sterilisation</b>          | EO Sterile                                                                                                                            |                   |     |                                                                                     |
| <b>Issue Date</b>             | 21st May 2024                                                                                                                         | <b>Version No</b> | R02 |                                                                                     |

|                     |                                                                                                                                   |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| <b>Intended use</b> | This device is intended to immobilise, and control used blades, sutures and the like (sharps) as employed in surgical procedures. |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------|

| Packaging    |        |                          |                |            |                      |
|--------------|--------|--------------------------|----------------|------------|----------------------|
| Product code | Colour | Dimension (mm)           | Items Per Pack | Qty- Inner | Qty – Shipper Carton |
| UN210        | White  | 120 x 146 x 3.2(nominal) | 1pcs           | 50pcs      | 300pcs               |

|                                                                                                                          |                                                                                                                                                                                                                        |             |     |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----|
| <b>Quality Certification</b>                                                                                             | ISO 13485:2016                                                                                                                                                                                                         |             |     |
| <b>Device Classification</b>                                                                                             | N/A                                                                                                                                                                                                                    | <b>Rule</b> | N/A |
| <b>Conformity Route</b>                                                                                                  | This product is not considered to be a medical device by the UK MHRA and is therefore not CE marked.                                                                                                                   |             |     |
| <b>Storage conditions</b>                                                                                                | Store in a cool dry place away from heat and direct sunlight                                                                                                                                                           |             |     |
| <b>Shelf life</b>                                                                                                        | 5 Years from manufacturing date if stored as recommended                                                                                                                                                               |             |     |
| <b>Contraindications/Warnings</b>                                                                                        | Once the sharps have been affixed to the adhesive section of the mat, it can be folded in half along the perforated hinge prior to disposal in a sharps bin.                                                           |             |     |
| <b>Markings</b>                                                                                                          | Universal logo, Product name, Code Ref, Lot no., Manufacture date, expiry date, Single use, EO -sterile, latex free, Contents sterile unless opened, damaged or wet, Manufacturer Name & Address, Distributor contact, |             |     |
| <b>Additional information</b>                                                                                            | Product is Latex-free.<br>Contents sterile unless opened, damaged or wet.                                                                                                                                              |             |     |
| <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             | 14/03/2024    | Update to Mediq UK Brand replacing DSN 105 | Elizabeth Ogunkolade |
| R02             | 21/05/2024    | Update Mediq Healthcare UK address         | Jack Wong            |
|                 |               |                                            |                      |
|                 |               |                                            |                      |

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