

# **TECHNICAL DATA SHEET**

# Earloop Face Mask: ASTM F2100 Level 3 Barrier Protection

# Intended Use

Procedure masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material. Latex free.

| ASTM F 2100 – Level 3 Barrier Protection |                     |   |  |  |  |  |
|--|---------------------|---|--|--|--|--|
| Characteristic                           | Testing Methodology | Acceptable Limits                               |  |  |  |  |
| Bacterial Filtration Efficiency (BFE)    | ASTM F2101          | BFE @ 3.0 µm large Bacteria ≥ 98%               |  |  |  |  |
| Differential Pressure (ΔP)               | EN 14683            | $\Delta P < 6.0 \text{ mm of H}_2\text{O/cm}^2$ |  |  |  |  |
| Particulate Filtration Efficiency (PFE)  | ASTM F2299          | PFE @ 0.1 μm large Latex particules ≥ 98%       |  |  |  |  |
| Fluid Resistance                         | ASTM F1862          | Resistant @ 160mmHg                             |  |  |  |  |
| Textile Flammability                     | 16 CFR 1610         | Class I flame spread                            |  |  |  |  |

| Characteristic       | Specification  |   |  |  |
|----------------------|--|---|--|--|
| Material Composition | Mask Body  | Outer Material                            | Spunbond Polypropylene (SBPP)                              |  |
|                      |  | Filter Layers                             | Melt Blown Polypropylene (MBPP) and<br>Antibacterial cloth |  |
|                      |  | Inner Material                            | Spunbond Polypropylene (SBPP)                              |  |
|                      | Nosepiece  | Galvanized Iron Wire                      |  |  |
|                      | Earloop  | Spandex Fiber                             |  |  |
| Description          | Omega pleats rectangular face masks with a shapeable nosepiece and two earloops present, one on each side, in order to hold mask in place. |   |  |  |
| Earloop Style        | Round knitted earloop  |   |  |  |
| Color                | Refer to Appendix 1  |   |  |  |
| Dimension            | Body Size  | Length                                    | 175 mm (6 %")  |  |
|                      |  | Width                                     | 95 mm (3 ¾")   |  |
|                      | Length of Earloop  | Regular                                   | 180 mm (7 <sup>3</sup> / <sub>32</sub> ")                  |  |
|                      | Upper Pleat Depth*   | 11 mm ( <sup>7</sup> / <sub>16</sub> ")   |  |  |
|                      | Lower Pleat Depth*   | 8 mm ( <sup>5</sup> / <sub>16</sub> ")    |  |  |
|                      | Length of Nosepiece  | 90 mm (3 <sup>35</sup> / <sub>64</sub> ") |  |  |

<sup>\*</sup> Measured on the outer material by inserting the ruler inside the pleat.

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#### Additional Information

| Storage Condition                            | Country of Origin |  |
|--|-------------------|--|
| Store under cool, clean, and dry conditions. | Tairren           |  |
| Avoid excessive heat (over 40°C or 104°F)    | Taiwan            |  |

# Appendix 1 List of Item Codes and Attributes

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# **Appendix 1 (List of items)**

# AMD Medicom Inc.

| Item Code | Description  | Packaging<br>Information                   | Color | Treatment   |
|-----------|--|--|-------|-------------|
| 410HAB    | Hedy SoftMask Defender Procedure Earloop Mask, Level 3 | 50 Masks/Box, 6 Boxes/Case, 300 Masks/Case | Blue  | Non-Sterile |
| 410HAG    | Hedy SoftMask Defender Procedure Earloop Mask, Level 3 | 50 Masks/Box, 6 Boxes/Case, 300 Masks/Case | Green | Non-Sterile |
| 410HAP    | Hedy SoftMask Defender Procedure Earloop Mask, Level 3 | 50 Masks/Box, 6 Boxes/Case, 300 Masks/Case | Pink  | Non-Sterile |
| 410HAW    | Hedy SoftMask Defender Procedure Earloop Mask, Level 3 | 50 Masks/Box, 6 Boxes/Case, 300 Masks/Case | White | Non-Sterile |

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