



DEVICE DETAILS

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| NAME OF DEVICE | ARMOUR 3PLY MEDICAL FACE MASK ULTRA THIN V-SHAPE 3D FACE MASK |
| ESTABLISHMENT NAME | SYMBION ASIA SDN BHD |
| REGISTRATION NO | GA6957522-98909 |
| BRAND NAME | ?SYMBION |
| DEVICE GROUPING TYPE | SINGLE |
| DEVICE DESCRIPTION | Surgical Mask is single use multi-layer mask with outer layer and inner layer (spun-bond polypropylene) that sandwich a melt-blown polypropylene filter material. There are 2 options for the surgical mask to be secured on user - via ear-loops or ties. Ear-loops are of urethane elastic fibre and latex-free; and ties are of spun-bond polypropylene and also latex-free. The nose piece is a pliable white aluminium strip, covered by PP covering. All of the materials used in the construction of the Surgical Mask are being used in currently marketed devices. |
| DEVICE INTENDED PURPOSE | Surgical mask (with different trade names: Face Mask, Surgical Mask, Surgical Face Mask) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. |
| VALIDITY DATE OF REGISTRATION | 01/08/2022 - 31/07/2027 |

LIST OF DEVICE

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