



DEVICE DETAILS

NAME OF DEVICE	ARMOUR 3PLY MEDICAL FACE MASK ULTRA THIN V-SHAPE 3D FACE MASK
ESTABLISHMENT NAME	SYMBION ASIA SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA6957522-98909
BRAND NAME	?SYMBION
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
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

NO	NAME OF DEVICE	IDENTIFIER
1	ARMOUR 3PLY MEDICAL FACE MASK ULTRA THIN V-SHAPE 3D FACE MASK	3PLY MEDICAL FACE MASK ULTRA THIN V-SHAPE 3D FACE MASK