



DEVICE DETAILS

NAME OF DEVICE	SURGICAL FACE MASK
ESTABLISHMENT NAME	ICON PACKAGING SDN BHD
REGISTRATION NO	GA2611821-78530
BRAND NAME	SUNWAY
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	A single use non sterile and latex free device made of non-woven and melt blown. Adjustable to fit faces of various shapes and sizes. The face mask tested for Bacterial Filtration Efficiency (BFE), Particle Filtration Efficiency (PFE) and Viral Filtration efficiency (VFE) that has sufficient protection against haze particles, dust and harmful droplets. It also high breathability, hypoallergenic, soft and lightweight.
DEVICE INTENDED PURPOSE	A mask is meant to help block large particle droplets, splashes or splatter that may contain germs (viruses & bacterial) keeping it from it reaching to your mouth. Face mask may also help to reduce the exposure of your saliva and respiratory secretion to others. This device, is appropriate to be use by healthcare professional during surgical procedures to protect both the patient and healthcare personnel.
VALIDITY DATE OF REGISTRATION	19/11/2021 - 18/11/2026

LIST OF DEVICE

MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
1	4 PLY SURGICAL FACE MASK	SW4001
2	4 PLY SURGICAL FACE MASK	SW4003
3	4 PLY SURGICAL FACE MASK	SW4006