



## DEVICE DETAILS

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|-------------------------------|--|
| NAME OF DEVICE                | SURGICAL FACE MASK   |
| ESTABLISHMENT NAME            | ICON PACKAGING SDN BHD   |
| ROLE OF ESTABLISHMENT         | MANUFACTURER   |
| REGISTRATION NO               | GA2221021-78544  |
| BRAND NAME                    | SUNWAY   |
| MEDICAL DEVICE CATEGORY       | SINGLE-USE DEVICES   |
| DEVICE GROUPING TYPE          | FAMILY   |
| DEVICE DESCRIPTION            | A single use non sterile and latex free device made of 2 layer of non woven and 1 layer of melt blown. Adjustable to fit faces of various shapes and sizes. The middle layer of face mask (Melt blown) which tested for Bacterial Filtration Efficiency that has sufficient protection against haze particles, dust and harmful droplets. It also high breathability, hypoallergenic, soft and lightweight. This device is appropriate to be use by healthcare professional during surgical procedures to protect both the patient and healthcare personnel. |
| DEVICE INTENDED PURPOSE       | A Surgical face mask is meant to help block large particle droplets, splashes or splatter that may contain germs (viruses & bacteria), keeping it from reaching to your mouth.   |
| VALIDITY DATE OF REGISTRATION | 19/11/2021 - 18/11/2026  |



## LIST OF DEVICE

| NO | NAME OF DEVICE           | IDENTIFIER |
|----|--------------------------|------------|
| 1  | 3 PLY SURGICAL FACE MASK | SW001      |
| 2  | 3 PLY SURGICAL FACE MASK | SW003      |
| 3  | 3 PLY SURGICAL FACE MASK | SW006      |