



DEVICE DETAILS

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| NAME OF DEVICE | KF99-SURGICAL FACE MASK |
| ESTABLISHMENT NAME | ICON PACKAGING SDN BHD |
| ROLE OF ESTABLISHMENT | MANUFACTURER |
| REGISTRATION NO | GA10810422-93028 |
| 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 non-woven, structural filter 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 | 23/05/2022 - 22/05/2027 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|-------------------------|------------|
| 1 | KF99 SURGICAL FACE MASK | SW7001 |
| 2 | KF99 SURGICAL FACE MASK | SW7006 |