

DEVICE DETAILS

| NAME OF DEVICE | KF94 protective face mask | | | |
|----------------------------------|--|--|--|--|
| ESTABLISHMENT NAME | JINGGA ANGGUN SDN BHD | | | |
| ROLE OF ESTABLISHMENT | MANUFACTURER | | | |
| REGISTRATION NO | GA3487823-146288 | | | |
| BRAND NAME | Omnifit | | | |
| MEDICAL DEVICE CATEGORY | SINGLE-USE DEVICES | | | |
| DEVICE GROUPING TYPE | SINGLE | | | |
| DEVICE DESCRIPTION | MODEL : SHIRUDO USA ASTM LEVEL 3 (HIGHEST) ASTM F2101-19 ASH20-073199-01 2021FM0094R01E BACTERIAL FILTRATION EFFICIENCY: >=99.9% PARTICLE FILTRATION EFFICIENCY : >= 98% PM 0.1 SUBMICRON FILTRATION FLUID RESISTANCE:>= 160mmHg BREATHABILITY -DELTA P:<6.0mmH20/cm2 FLAMMABILITY : CLASS 1 PRODUCT IS HYPOALLERGENIC,LATEX AND FIBERGLASS-FREE RECOMMENDED FOR SENSITIVE SKIN SOFT & LIGHTWEIGHT | | | |
| DEVICE INTENDED PURPOSE | This product is intended for general purpose infection control practices. When properly worn, it reduces potential contact by the wearer to blood and bodily fluids. | | | |
| VALIDITY DATE OF REGISTRATION | 28/08/2023 - 27/08/2028 | | | |
| | Micdical Device | | | |
| | MALAYSIA | | | |

| LIST OF DEVICE | | MEDICAL DEVICE AUTHORITY | | |
|----------------|---------------------------|--------------------------|------------|------------|
| NO | NAME OF DEVICE | | IDENTIFIER | |
| 1 | KF94 protective face mask | | KF94 | 4-NB/B-002 |