



DEVICE DETAILS

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| NAME OF DEVICE | DISPOSABLE MEDICAL FACE MASK (TYPE IIR) |
| ESTABLISHMENT NAME | SIMPLY K SDN BHD |
| REGISTRATION NO | GA7405121-66478 |
| BRAND NAME | SIMPLY K |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | Disposable medical face masks comply with EN 14683 'Type IIR' embedded with nose clip and ear loops or head loops. This medical face mask made of 3-ply of premium non-woven fabric with Bacterial Filtration Efficiency (BFE) >98 and Splash Resistance Pressure > 16.0 kPa. |
| DEVICE INTENDED PURPOSE | Disposable Medical face mask that covers the user's nose and mouth and provides a physical barrier from transmission of viruses, microorganisms and dust. It is intended to be use by healthcare provider and other persons for medical purposes and to control infectious diseases, particularly in epidemic or pandemic situations. |
| VALIDITY DATE OF REGISTRATION | 13/07/2021 - 12/07/2026 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|------------------------------|---------------------------------------|
| 1 | DISPOSABLE MEDICAL FACE MASK | ADULT DISPOSABLE MEDICAL FACE MASK |
| 2 | DISPOSABLE MEDICAL FACE MASK | CHILDREN DISPOSABLE MEDICAL FACE MASK |