



DEVICE DETAILS

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| NAME OF DEVICE | Medical Face Mask with Ear Loops |
| ESTABLISHMENT NAME | PERKASA INTERNATIONAL SDN BHD |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GA5201921-63016 |
| BRAND NAME | Gemtier Medical (shanghai) inc |
| MEDICAL DEVICE CATEGORY | SINGLE-USE DEVICES |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | Meets ASTM Level 3 requirements, Higher Efficiency Filtration, PTFE, Excellent breathability due to high porosity and ultra-thin thickness, Filtered protective isolation face masks with elastic ear loops, Breathable, anti-dust, anti-smog, Not made with natural rubber latex, Fluid protection, FDA approved |
| DEVICE INTENDED PURPOSE | Type I Medical face masks should only use for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or other medical settings with similar requirements. |
| VALIDITY DATE OF REGISTRATION | 08/06/2021 - 07/06/2026 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|-------------------|----------------|------------|
| No results found. | | |