



DEVICE DETAILS

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.		