



## DEVICE DETAILS

NAME OF DEVICE	Protective Face Mask for Medical Use
ESTABLISHMENT NAME	FERMETEC MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA4266720-49430
BRAND NAME	Tai Da Kang
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The product consists of mask body, nose clip and mask belt. This product consists of outer PP non-woven fabric, middle layer PP hot water cotton, filter layer PP melt spray cloth, inner layer PP non-woven fabric four layers
DEVICE INTENDED PURPOSE	The scope of application is to applicable to the face of a person wearing contact with a virus in a material institution and is used to prevent the transmission of the virus from the patient to the medical staff. It can be used as highest protection in operating theatre for surgeons too. Suggested settings and applications: Operating Rooms, Clinics, TB Wards, Patient Care, Labour and Delivery, Infection Control Practices, frontline healthcare workers for COVID-19, Laboratory, emergency or pandemic preparedness planning, stockpiling, etc.
VALIDITY DATE OF REGISTRATION	11/11/2020 - 10/11/2025

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Protective face mask for medical use	-
2	Protective face mask for medical use	-