



DEVICE DETAILS

NAME OF DEVICE	Disposable Surgical Face Mask
ESTABLISHMENT NAME	KOMARK MASK (M) SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA5189323-129687
BRAND NAME	Komark Mask
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Surgical Disposable Face Mask is an effective form PPE to provide respiratory protection and can prevent the transmission of contagious respiratory droplets by infected individuals. Product Description: • Particulate Matter rating, PM 0.1 • Bacterial Filtration Efficiency, BFE ≥98% • Particle Filtration Efficiency, PFE ≥98% • Viral Filtration Efficiency, VFE ≥99% • Synthetic Blood Splash Resistance, 160mmHg • Flammability, Class 1 There are two type: Tie On Disposable Surgical Face Mask and Ear Loop Disposable Surgical Face Mask. Sterilized by ethylene oxide. Disposable and single use.
DEVICE INTENDED PURPOSE	The surgical disposable face mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluid and particulate material. Surgical face mask also used for infection control practices to reduce the potential exposure to blood and body fluid.
VALIDITY DATE OF REGISTRATION	08/05/2023 - 07/05/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Disposable surgical face mask	FMS3PA-TO
2	Disposable surgical face mask	FMS3PA-TO
3	Disposable surgical face mask	FMS3PA-TO
4	Disposable surgical face mask	FMS3PA-TO
5	Disposable surgical face mask	FMS3PA-TO
6	Disposable surgical face mask	FMS3PA-EL