



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	Disposable Surgical Face Mask - Non Sterile
<b>ESTABLISHMENT NAME</b>	KOMARK MASK (M) SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	MANUFACTURER
<b>REGISTRATION NO</b>	GA2171623-137479
<b>BRAND NAME</b>	Komark Mask
<b>MEDICAL DEVICE CATEGORY</b>	SINGLE-USE DEVICES
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	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: <ul style="list-style-type: none"> <li>• Particulate Matter rating, PM 0.1</li> <li>• Bacterial Filtration Efficiency, BFE <math>\geq 98\%</math></li> <li>• Particle Filtration Efficiency, PFE <math>\geq 98\%</math></li> <li>• Viral Filtration Efficiency, VFE <math>\geq 99\%</math></li> <li>• Synthetic Blood Splash Resistance, 160mmHg</li> <li>• Flammability, Class 1</li> </ul> There are two type: Tie On Disposable Surgical Face Mask and Ear Loop Disposable Surgical Face Mask. Non sterile, disposable and single use.
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	28/06/2023 - 27/06/2028

## 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