



DEVICE DETAILS

NAME OF DEVICE	PARAGON Surgical Face Mask
ESTABLISHMENT NAME	PARAGON MEDICARE SUPPLIES SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA1755920-49371
BRAND NAME	PARAGON
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	A single-use and non-sterile medical device made of non-woven fabric. It consists of a mask body, a nose clip and ear loops or with ties. The mask body is composed of an inner and outer layer of spun-bond non-woven fabric and the middle layer of melt-blown non-woven fabric with a total of 3 layers.
DEVICE INTENDED PURPOSE	It is a device used to cover the mouth and nose. It serves as a barrier for contaminants being released from the mouth of a sick person and spread to the environment or to be inhaled by people in the public. It is used in surgery, medical and dental examinations, industrial sites, general cleaning, preparation of food or worn when airborne diseases caused an outbreak.
VALIDITY DATE OF REGISTRATION	09/11/2020 - 08/11/2025

LIST OF DEVICE

MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
1	Surgical Face Mask	Adult
2	Surgical Face Mask	Adult
3	Surgical Face Mask	Child