

DEVICE DETAILS		
NAME OF DEVICE	PARAGON FACE MASK	
ESTABLISHMENT NAME	PARAGON MEDICARE SUPPLIES SDN. BHD.	
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE	
REGISTRATION NO	GA4230820-48792	
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 earloops or with ties. The mask body is composed of an inner and outer layer of spunbond 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 also in surgery, medical and dental examination, industrial sites, general cleaning or preparation of food or worn when airborne diseases caused an outbreak.	
VALIDITY DATE OF REGISTRATION	02/11/2020 - 01/11/2025	

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