



DEVICE DETAILS

NAME OF DEVICE	Disposable Medical Face Mask
ESTABLISHMENT NAME	SIMPLY K SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA2640421-68154
BRAND NAME	POP K
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Disposable medical face masks comply with EN 14683 'Type IIR' embedded with nose clip and ear loops or head loops. This medical face mask made of 3-ply of premium non-woven fabric with Bacterial Filtration Efficiency (BFE) >98 and Splash Resistance Pressure > 16.0 kPa.
DEVICE INTENDED PURPOSE	Disposable Medical face mask that covers the user's nose and mouth and provides a physical barrier from transmission of viruses, microorganisms and dust. It is intended to be use by healthcare provider and other persons for medical purposes and to control infectious diseases, particularly in epidemic or pandemic situations.
VALIDITY DATE OF REGISTRATION	03/08/2021 - 02/08/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	DISPOSABLE SURGICAL FACE MASK	ADULT SURGICAL FACE MASK - EAR LOOP
2	DISPOSABLE SURGICAL FACE MASK	ADULT SURGICAL FACE MASK - HEAD LOOP
3	DISPOSABLE SURGICAL FACE MASK	CHILDREN SURGICAL FACE MASK - EAR LOOP
4	DISPOSABLE SURGICAL FACE MASK	CHILDREN SURGICAL FACE MASK - HEAD LOOP