



DEVICE DETAILS

NAME OF DEVICE	DISPOSABLE SURGICAL FACE MASK
ESTABLISHMENT NAME	SIMPLY K SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA8505621-72954
BRAND NAME	SIMPLY K
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Disposable surgical face masks comply with EN 14683 'Type IIR' embedded with nose clip and ear loops or head loops. This surgical 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 Surgical face mask that covers the user's nose and mouth and provides a physical barrier from transmission of viruses, microorganisms and dust. It is suitable to be use for surgical procedures to protect both patient and healthcare provider.
VALIDITY DATE OF REGISTRATION	22/09/2021 - 21/09/2026

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