



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	DISPOSABLE SURGICAL FACE MASK
<b>ESTABLISHMENT NAME</b>	SIMPLY K SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	MANUFACTURER
<b>REGISTRATION NO</b>	GA8505621-72954
<b>BRAND NAME</b>	SIMPLY K
<b>MEDICAL DEVICE CATEGORY</b>	SINGLE-USE DEVICES
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	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.
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	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