

DEVICE DETAILS		
NAME OF DEVICE	DISPOSABLE SURGICAL FACE MASK	
ESTABLISHMENT NAME	SIMPLY K SDN BHD	
REGISTRATION NO	GA8505621-72954	
BRAND NAME	SIMPLY K	
DEVICE GROUPING TYPE	FAMILY	
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 DEVICE AUTHORITY
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