



DEVICE DETAILS

NAME OF DEVICE	DISPOSABLE MEDICAL FACE MASK (TYPE IIR)
ESTABLISHMENT NAME	SIMPLY K SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA7405121-66478
BRAND NAME	SIMPLY 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	13/07/2021 - 12/07/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	DISPOSABLE MEDICAL FACE MASK	ADULT DISPOSABLE MEDICAL FACE MASK
2	DISPOSABLE MEDICAL FACE MASK	CHILDREN DISPOSABLE MEDICAL FACE MASK