



DEVICE DETAILS

NAME OF DEVICE	DISPOSABLE MEDICAL FACE MASK
ESTABLISHMENT NAME	SIMPLY K SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA8718921-52067
BRAND NAME	SIMPLY K
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Disposable medical face masks embedded with nose clip and ear loops or with ties. This medical face mask made of 3-ply of premium non-woven fabric with Bacterial Filtration Efficiency (BFE) >95% and Particle Filtration Efficiency (PFE) >95%.
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	12/01/2021 - 11/01/2026

LIST OF DEVICE



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