



DEVICE DETAILS

NAME OF DEVICE	Face Mask
ESTABLISHMENT NAME	BERGAMOT SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA3628622-111965
BRAND NAME	Halo
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Medical face mask, single-use
DEVICE INTENDED PURPOSE	To be placed over the mouth and nose of a healthcare personnel to protect both the patient and healthcare personnel from transfer of microorganisms, particulate material, blood and body fluids. These face masks are not intended for surgical operation
VALIDITY DATE OF REGISTRATION	16/12/2022 - 15/12/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Halo KF94 4-Ply Face Mask Negative Oxygen Ion (Earloop)	OV315
2	Halo KF94 4-Ply Face Mask Negative Oxygen Ion (Headloop)	OV325
3	Halo Coloured KF94 4-Ply Face Mask (Earloop)	OV335