




DEVICE DETAILS

NAME OF DEVICE	Face Mask
ESTABLISHMENT NAME	BERGAMOT SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA5288123-123867
BRAND NAME	Zen Mask
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Medical face mask and single-use device
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	12/03/2023 - 11/03/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Face Mask 	B0511