

DEVICE DETAILS		
NAME OF DEVICE	Face Mask	
ESTABLISHMENT NAME	BERGAMOT SDN BHD	
REGISTRATION NO	GA5288123-123867	
BRAND NAME	Zen Mask	
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	Medical Device B0511	
	5000	AUTRORITY MALAYSIA	

MEDICAL DEVICE AUTHORITY