



DEVICE DETAILS

NAME OF DEVICE	Face Mask
ESTABLISHMENT NAME	BERGAMOT SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA4308421-58036
BRAND NAME	Bergamot
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	To be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The mask is a single use, disposable device, provided non-sterile
DEVICE INTENDED PURPOSE	To be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The mask is a single use, disposable device, provided non-sterile
VALIDITY DATE OF REGISTRATION	30/03/2021 - 29/03/2026

LIST OF DEVICE

MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
1	Bergamot 3-Ply Face Mask (Earloop)	B0501
2	Bergamot 3-Ply Face Mask (Tie On)	B0502
3	Bergamot 3-Ply Face Mask (Headloop)	B0507
4	Bergamot 3-Ply Face Mask Basic Medical (Earloop)	B0519
5	Bergamot 4-Ply Face Mask (Earloop)	B0504
6	Bergamot 4-Ply Vanscent Face Mask (Earloop)	VS8011
7	Bergamot Copper X 4-Ply Medical Face Mask (Earloop)	XV613
8	Bergamot 3-Ply Medical Kids Face Mask (Earloop)	B0518
9	Bergamot 4-Ply Medical Face Mask (Earloop)	BV612-AG
10	Bergamot 4-Ply Medical Face Mask (Earloop)	BV612-GN

NO	NAME OF DEVICE	IDENTIFIER
11	Bergamot 4-Ply Medical Face Mask (Earloop)	BV612-PK
12	Bergamot 4-Ply Medical Face Mask (Earloop)	BV612-VT
13	Bergamot 4-Ply Medical Face Mask (Earloop)	BV612-YL
14	Bergamot Cool Series Cordial Bears 4-Ply Medical Adults Face Mask (Earloop)	B05-CB-A05
15	Bergamot Cool Series Cordial Bears 4-Ply Medical Kids Face Mask (Earloop)	B05-CB-K05
16	Bergamot 3-Ply Lint Free Medical Face Mask (Headloop)	B0507-02

