



## 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



| 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   |
| 11 | Bergamot 4-Ply Medical Face Mask (Earloop)          | BV612-PK   |

| NO | NAME OF DEVICE                                                              | IDENTIFIER |
|----|-----------------------------------------------------------------------------|------------|
| 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   |
| 17 | Bergamot 3-Ply Face Mask Basic Medical (Earloop)                            | B0519-1    |
| 18 | Bergamot 3-Ply Face Mask Basic Medical (Earloop)                            | B0519-2    |
| 19 | Bergamot 3-Ply Lint Free Medical Face Mask (Headloop)                       | B0507-2    |

