



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	Face Mask
<b>ESTABLISHMENT NAME</b>	BERGAMOT SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GA9225621-80568
<b>BRAND NAME</b>	Halo
<b>MEDICAL DEVICE CATEGORY</b>	SINGLE-USE DEVICES
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	Medical face mask, single-use
<b>DEVICE INTENDED PURPOSE</b>	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
<b>VALIDITY DATE OF REGISTRATION</b>	06/12/2021 - 05/12/2026

## 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