



DEVICE DETAILS

NAME OF DEVICE	OuFinity Surgical Face Mask
ESTABLISHMENT NAME	GPI TECHNOLOGY SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA6649821-78710
BRAND NAME	OuFinity
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	A flexible, loose-fitting surgical face mask designed to be placed over the mouth and/or nose of a user to permit normal breathing while protecting the patient and wearer from the transfer of large particles (e.g., blood, body fluids, and airborne particulate materials) during medical/surgical procedures and patient examination; it is not a form-shaped filtering device (i.e., not a respirator).
DEVICE INTENDED PURPOSE	These masks could be used by the general public, patients and other persons such as doctor, hospital staff to reduce the risk of spread of infections particularly in epidemic or pandemic situations by cover user's nose and mouth that provides a physical barrier from transmission of viruses, microorganisms, and body fluids.
VALIDITY DATE OF REGISTRATION	21/11/2021 - 20/11/2026



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	OuFinity Surgical Face Mask	A102 Premium
2	OuFinity Surgical Face Mask	A103 Ultra