



DEVICE DETAILS

NAME OF DEVICE	UCARE Surgical Face Mask
ESTABLISHMENT NAME	UPA HEALTHCARE PRODUCTS SDN. BHD.
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA7124421-70592
BRAND NAME	UCARE
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	1. A flexible, loose-fitting mask designed to be placed over the mouth and/or nose of a healthcare worker 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 procedures and patient examination; it is not a form-shaped filtering device (i.e., not a respirator). It is made of a flexible, porous fabric or paper material and is typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or transparent face/eye visor intended to protect the upper face/eyes from debris/fluid. This is a single-use device. 2. These masks could be used by the general public, patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.
DEVICE INTENDED PURPOSE	1. A flexible, loose-fitting mask designed to be placed over the mouth and/or nose of a healthcare worker 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 procedures and patient examination; it is not a form-shaped filtering device (i.e., not a respirator). It is made of a flexible, porous fabric or paper material and is typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or transparent face/eye visor intended to protect the upper face/eyes from debris/fluid. This is a single-use device. 2. These masks could be used by the general public, patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.
VALIDITY DATE OF REGISTRATION	06/09/2021 - 05/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Surgical / Medical Face Mask, Single-Use [UCARE Surgical Face Mask][Normal Ear Loop]	9551008980166
2	Surgical / Medical Face Mask, Single-Use [UCARE Surgical Face Mask][Wider Ear Loop]	9551008980173

NO	NAME OF DEVICE	IDENTIFIER
3	Surgical / Medical Face Mask, Single-Use [UCARE Surgical Face Mask][Normal Ear Loop]	9551008980128
4	Surgical / Medical Face Mask, Single-Use [UCARE Surgical Face Mask][Wider Ear Loop]	9551008980135
5	Surgical / Medical Face Mask, Single-Use [UCARE Surgical Face Mask][Normal Ear Loop]	9551008980210
6	Surgical / Medical Face Mask, Single-Use [UCARE Surgical Face Mask][Normal Ear Loop]	9551008980258



MEDICAL DEVICE AUTHORITY