



DEVICE DETAILS

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| 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 |
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| 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