



DEVICE DETAILS

NAME OF DEVICE	UCARE KN95 RESPIRATOR
ESTABLISHMENT NAME	UPA HEALTHCARE PRODUCTS SDN. BHD.
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA2781921-66738
BRAND NAME	UCARE
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	A form-shaped filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) when considered necessary (e.g., viral epidemic). It is typically made of multiple layers of non-woven polymers to produce a soft, flexible mask that will create an airtight seal against the user's face and typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or an exhalation valve. This is a single-use device.
DEVICE INTENDED PURPOSE	A form-shaped filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) when considered necessary (e.g., viral epidemic). It is typically made of multiple layers of non-woven polymers to produce a soft, flexible mask that will create an airtight seal against the user's face and typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or an exhalation valve. This is a single-use device.
VALIDITY DATE OF REGISTRATION	16/07/2021 - 15/07/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Respirator, Single-Use [UCARE KN95 Respirator]	9551008980074
2	Respirator, Single-Use [UCARE KN95 Respirator][Small]	9551008980142