



DEVICE DETAILS

NAME OF DEVICE	Disposable Medical Face Mask
ESTABLISHMENT NAME	UVA INTERNATIONAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA4580621-68902
BRAND NAME	SAFEPROTECT
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Disposable Medical Face Masks, designed and manufactured to cover the wearers' mouth, nose, and jaw, suitable for use in a general medical setting as a disposable face mask to block the exhalation or ejection of contaminants from the mouth and nose. It is a single-use, multi-layer mask with an outer layer and inner layer (spun-bond polypropylene) that sandwich a melt-blown polypropylene filter material. There are 3 options for the disposable medical mask to be secured on the user - via earloops, ties or head-loop. Earloops and head-loops are of 20% spandex + 80% draw textured yarn, and ties are latex-free spun-bond polypropylene. The nose piece is a pliable white aluminium strip, covered by PP covering. All of the materials used in the construction of the disposable medical mask are being used in currently marketed devices.
DEVICE INTENDED PURPOSE	The disposable medical mask is intended for single use by operating room personal and other general healthcare workers to protect both patients and healthcare workers against the transfer of microorganisms, blood and body fluids, and airborne particulates.
VALIDITY DATE OF REGISTRATION	14/08/2021 - 13/08/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Disposable Medical Face Mask	M1005
2	Disposable Medical Face Mask	M1006