



DEVICE DETAILS

NAME OF DEVICE	SUPER SURGICAL FACE MASK
ESTABLISHMENT NAME	SIN HUAT PRESS (MELAKA) SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA3111521-52105
BRAND NAME	SUPER
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Procedure surgical face mask is a 3-ply disposable mask consisting of 3 layers, which are the outer hydrophobic non-woven layer, the middle melt-blown layer, and an inner soft absorbent non-woven layer, with ear loops at both sides of the masks. It is meant for single use and intended for protection against transfer of microorganism, droplets and airborne particulate. The outer non-woven layer is a water proof layer to prevent absorption of droplets while the meltblown layers serves to contain droplets by electrostatically adsorbing them on the surface hence it cannot infiltrate the mask; whereas the inner layer is intended to absorb water, sweat and saliva. It comes with ear loops and a nose strip.
DEVICE INTENDED PURPOSE	Intended for single use to protect against transfers of microorganisms, droplets and airborne particulates by preventing large droplets or splatters that could possibly contains microorganism from entering the body through nose and mouth as well as to prevent from transmitting droplets or splatters that could possibly contains microorganism to others.
VALIDITY DATE OF REGISTRATION	12/01/2021 - 11/01/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	SUPER SURGICAL FACE MASK	SM-SFM-3001-0