



DEVICE DETAILS

NAME OF DEVICE	Medical Face Mask
ESTABLISHMENT NAME	TRIPLE HARDWARE (M) SDN. BHD.
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA10771821-74228
BRAND NAME	TRIPLE
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Medical masks are made up of nose strip , elastic earloops and multi-layered structure of fabric. The inner and outer layer are made of non-woven materials with the centre layer made of meltblown fabric act as filter. Medical masks offer high filtration efficiency, edequate breathability and reasonable fluid penetration resistance. Their performance characteristic are tested according to a set of standardized test methods base on international standards such as ASTM F-2100, EN14683 or equivalent to verify that they meet prescribed requirements for bacteria and particles filtration efficiency (at least 95%), breathability, splash resistance etc.
DEVICE INTENDED PURPOSE	Medical masks offer "source control" and protection for the wearer against exposure to splashes and sprays of infectious materials from others. Therefore, in situations where an individuals is in contact with an infected or potentially infected individual, a medical mask is recommended. "Source control" refers to preventing the wearer's respiratory droplets from travelling into the air and onto other people when the person wearing the mask coughs, sneezes, talk etc. * A single-use product. It is advisable not to re-use a contaminated or soil mask.
VALIDITY DATE OF REGISTRATION	29/09/2021 - 28/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Medical Face Mask	TH-FM-FM3