



DEVICE DETAILS

NAME OF DEVICE	Non-Woven Disposable Surgical Face Mask
ESTABLISHMENT NAME	TPX MEDIK SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA4779421-66780
BRAND NAME	Skin Hygiene 3 PLY Surgical Face Mask
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	3-Ply disposable surgical face mask is a non-woven material that offers filtration-efficient, fluid resistant, superior comfort and breathability to help reduce wearer to exposure of potentially infectious particles, blood and body fluids.
DEVICE INTENDED PURPOSE	3-Ply Disposable surgical Face Mask is to be used as a barrier to prevent air-borne transfer of infectious, large particle droplets and various micro-organisms. It is designed to be used in hospital, clinic, operating theater and clean room environment, etc.
VALIDITY DATE OF REGISTRATION	16/07/2021 - 15/07/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Non-Woven Disposable Surgical Face Mask, 17.5cm x 9.5cm	127
2	Non-Woven Disposable Surgical Face Mask, 14.5cm x 9.5cm	126