



DEVICE DETAILS

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| 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 |