



## DEVICE DETAILS

|                               |   |
|-------------------------------|---|
| NAME OF DEVICE                | SURGICAL FACE MASK  |
| ESTABLISHMENT NAME            | EPSILON MEDICAL DEVICES SDN BHD   |
| REGISTRATION NO               | GA4176821-72526   |
| BRAND NAME                    | Epsilon Medical Devices   |
| DEVICE GROUPING TYPE          | FAMILY  |
| DEVICE DESCRIPTION            | Surgical face masks are rectangular in shape and consist of a mask, nose clamp and an ear loops. The face masks covers the mouth and nose providing a barrier to minimise the direct transmission of infective agents. The mask consist of three layer and each layer comprises of fine to very fine fibres manufactured from non-woven materials (e.g. polypropylene, polyethylene or cellulose). The surgical face mask provide high filtration, excellent breathability and fluid resistance. The use of surgical face masks in the community may divert this critical resource from the healthcare professionals (in an operating room or other medical settings) and others who need them the most. The surgical face mask is for single use only. |
| DEVICE INTENDED PURPOSE       | Surgical face mask used to protect the healthcare professionals from transmission of infective agents and in some circumstances protect against splashes of potentially contaminated liquids. Surgical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.  |
| VALIDITY DATE OF REGISTRATION | 20/09/2021 - 19/09/2026   |

MEDICAL DEVICE AUTHORITY

## LIST OF DEVICE

| NO | NAME OF DEVICE                    | IDENTIFIER |
|----|-----------------------------------|------------|
| 1  | SURGICAL FACE MASK - TYPE IIR     | FGFMA001   |
| 2  | SURGICAL FACE MASK (E) - TYPE IIR | FGFMA002   |