



DEVICE DETAILS

NAME OF DEVICE	SURGICAL FACE MASK
ESTABLISHMENT NAME	EPSILON MEDICAL DEVICES SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA4176821-72526
BRAND NAME	Epsilon Medical Devices
MEDICAL DEVICE CATEGORY	SINGLE-USE 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

LIST OF DEVICE

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