



DEVICE DETAILS

NAME OF DEVICE	MEDICAL FACE MASK
ESTABLISHMENT NAME	EPSILON MEDICAL DEVICES SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA6395720-49447
BRAND NAME	Epsilon
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Medical 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 minimize 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 medical face mask provide high filtration, excellent breathability and fluid resistance. The use of medical 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 medical face mask is for single use only.
DEVICE INTENDED PURPOSE	Medical face mask used to protect the user from transmission of infective agents and in some circumstances protect user against splashes of potentially contaminated liquids. Medical 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	12/11/2020 - 11/11/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	MEDICAL FACE MASK	FGFMA001