



DEVICE DETAILS

NAME OF DEVICE	FACE MASK
ESTABLISHMENT NAME	MEDIGATE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA7293926-223946
BRAND NAME	LEBOO
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Single-use, disposable device worn over the nose and mouth to provide a physical barrier that reduces the risk of transmission of infectious agents between the wearer and the surrounding environment. It is commonly used by healthcare personnel, patients, and the public in clinical, surgical, or general healthcare settings.
DEVICE INTENDED PURPOSE	To protect the patient from infective agents by covering the mouth and nose of medical staff. And it is also to protect the medical staff against splashes of potentially contaminated liquids.
VALIDITY DATE OF REGISTRATION	27/01/2026 - 26/01/2031

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Face Mask	N77A02
2	Face Mask	N77A01