



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	PELANGI PROGRESIF SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC6325423-142656
BRAND NAME	BIOLIGHT
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Patient Monitor M800 monitor significant vital sign parameters of patients, including SpO2 and pulse rate.
DEVICE INTENDED PURPOSE	The M800 handheld monitor is intended for continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric and neonatal patients in hospital, hospital type facilities, transport and mobile environments as well as in the home care environment.
VALIDITY DATE OF REGISTRATION	25/07/2023 - 24/07/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Patient monitor	M800
2	BLT digital SpO2 adult reusable sensor	15-100-0013
3	AA alkaline battery	AA Battery
4	LB-03 Lithium battery	12-033-0001
5	M800 Battery charger stand & AC-DC adapter	23-033-0001
6	ECG Cable	15-031-0004
7	Disposable Adhesive Electrodes	15-100-0008
8	User's Manual	Manual