



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	PULSE OXIMETER
<b>ESTABLISHMENT NAME</b>	PELANGI PROGRESIF SDN. BHD.
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GC6325423-142656
<b>BRAND NAME</b>	BIOLIGHT
<b>MEDICAL DEVICE CATEGORY</b>	MD 1302 - Monitoring devices of vital physiological parameters
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	Patient Monitor M800 monitor significant vital sign parameters of patients, including SpO2 and pulse rate.
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	25/07/2023 - 24/07/2028

## LIST OF DEVICE



MEDICAL DEVICE AUTHORITY

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