



## DEVICE DETAILS

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|--------------------------------------|--|
| <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

| 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      |