



DEVICE DETAILS

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| NAME OF DEVICE | FINGERTIP PULSE OXIMETER |
| ESTABLISHMENT NAME | ONECARE BIOTECH SDN BHD |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GC3880222-83400 |
| BRAND NAME | LEPU |
| MEDICAL DEVICE CATEGORY | MD 1100 - GENERAL ACTIVE MEDICAL DEVICES |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | The product is mainly indicated for measurement of human Oxygen Saturation (SpO ₂), Pulse Rate (PR) and PI(Perfusion Index). The product has visual prompts and verbal prompts , such as finger out and pulse sound (optional). The applied part of this device is silica gel pad. The measuring principles of pulse oximeter is based on Lambert Beer law, The spectrum absorption characteristics is different of Reductive hemoglobin(RHb) and Oxyhemoglobin(Hbo ₂) in red light and nearinfrared light zones. The pulse oximeter calculate Spo ₂ ,PR and PI from the light intensity absorption difference by measuring the ratio of absorbed red and infrared light with each pulse. |
| DEVICE INTENDED PURPOSE | The LOX100 Fingertip Oximeter is intended for use in homes or hospitals for noninvasive measurement of oxygen saturation, pulse rate and perfusion index. The device can be used for both children and adults. This device is intended only for spotchecking. |
| VALIDITY DATE OF REGISTRATION | 16/01/2022 - 15/01/2027 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
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| 1 | Fingertip Pulse Oxymeter (Blue) | LOX100A |
| 2 | Fingertip Pulse Oxymeter (Green) | LOX100B |
| 3 | Fingertip Pulse Oxymeter (Cyan) | LOX100C |
| 4 | Fingertip Pulse Oxymeter (Yellow) | LOX100D |