



DEVICE DETAILS

| | |
|--------------------------------------|--|
| NAME OF DEVICE | FINGERTIP PULSE OXIMETER |
| ESTABLISHMENT NAME | FELCO MEDICAL SUPPLIES SDN BHD |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GC2231721-73320 |
| BRAND NAME | HEARTCARE |
| MEDICAL DEVICE CATEGORY | MD 1300 - MONITORING DEVICES |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | <p>The product is mainly indicated for measurement of human Oxygen Saturation (SpO₂), Pulse Rate (PR) and PI (Perfusion Index). The product has visual prompts and verbal prompts (optional), such as finger out and pulse sound (optional). The applied part of this device is silicone sleeve. The measuring principles of pulse oximeter is based on Lambert-Beer law, the spectrum absorption characteristics is different of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO₂) in red light and near-infrared light zones. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO₂) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse.</p> |
| DEVICE INTENDED PURPOSE | Fingertip pulse oximeter is intended for noninvasive measurement of oxygen saturation, pulse rate and perfusion index in homecare and hospitals, applicable for children and adult. |
| VALIDITY DATE OF REGISTRATION | 23/09/2021 - 22/09/2026 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|--------------------------|------------|
| 1 | Fingertip Pulse Oxymeter | LOX100A |
| 2 | Fingertip Pulse Oxymeter | LOX100B |
| 3 | Fingertip Pulse Oxymeter | LOX100C |
| 4 | Fingertip Pulse Oxymeter | LOX100D |