



DEVICE DETAILS

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| NAME OF DEVICE | HANDHELD PULSE OXIMETER (SP-20) |
| ESTABLISHMENT NAME | LEPU COMMERCE(MALAYSIA) SDN.BHD |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GC4638724-178881 |
| BRAND NAME | LEPU MEDICAL |
| MEDICAL DEVICE CATEGORY | MD 1302 - Monitoring devices of vital physiological parameters |
| DEVICE GROUPING TYPE | SYSTEM |
| DEVICE DESCRIPTION | This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO ₂), and temperature (optional). It is applicable for detecting SpO ₂ , pulse rate, and temperature of adult and neonate patients in clinical institutions and homes. ● It is applicable for adults, paediatric, and neonate measurements in hospital and home. ● Measuring SpO ₂ , Pulse Rate and Temperature (optional) ● 3.5-inch TFT display of PI%, plethysmograph and pulse bar ● 16 user IDs for marking data and can be added ● A built-on holder for convenient standing on desktop ● The base is used to hold the oximeter, and also for charging. ● Lithium battery up to 18 hours ● More than 500 hours SpO ₂ and PR data storage ● PC software for data management. ● Audible and visual alert function is available ● Auto power off is available |
| DEVICE INTENDED PURPOSE | This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO ₂), and temperature (optional). It is applicable for detecting SpO ₂ , pulse rate, and temperature of adult and neonate patients in clinical institutions and homes. |
| VALIDITY DATE OF REGISTRATION | 08/08/2024 - 07/08/2029 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|-------------------------|---------------|
| 1 | Handheld Pulse Oximeter | SP-20 |
| 2 | SpO ₂ probe | KS-AC01 |
| 3 | SpO ₂ probe | KS-AR02 |
| 4 | SpO ₂ probe | KS-AYW02 |
| 5 | SpO ₂ probe | KS-ALW025 |
| 6 | SpO ₂ probe | Analog Y-Type |

| NO | NAME OF DEVICE | IDENTIFIER |
|-----------|-----------------------|-------------------|
| 7 | SpO2 probe | Analog D-Type |
| 8 | Oximeter rubber cover | KRK315 |
| 9 | Charging base | LXCP12-005 |
| 10 | Temperature probe | KT-602 |
| 11 | Charging cable | USB-A |
| 12 | USB data cable | USB-A |



MEDICAL DEVICE AUTHORITY