

DEVICE DETAILS

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| NAME OF DEVICE | PULSE OXIMETER CMS50DL2 |
| ESTABLISHMENT NAME | SOLID INTELLECTUAL SDN. BHD. |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GC1687922-85802 |
| BRAND NAME | CMS50DL2 |
| MEDICAL DEVICE CATEGORY | MD 1302 - Monitoring devices of vital physiological parameters |
| DEVICE GROUPING TYPE | SINGLE |
| DEVICE DESCRIPTION | The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). This device is not intended for continuous monitoring. The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of Hemoglobin Saturation. The device doesn't incorporate tissues, or blood products. The device is reusable, noninvasive, implantable device. |
| DEVICE INTENDED PURPOSE | The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care ect.). This device is not intended for continuous monitoring. |
| VALIDITY DATE OF REGISTRATION | 27/01/2022 - 26/01/2027 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|-------------------------|------------|
| 1 | PULSE OXIMETER CMS50DL2 | CMS50DL2 |