



DEVICE DETAILS

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| NAME OF DEVICE | SHENZHEN AEON TECHNOLOGY PULSE OXIMETER |
| ESTABLISHMENT NAME | SUNLIFE MEDIC SDN BHD |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GC85721538418 |
| BRAND NAME | A300, A330, A360 |
| MEDICAL DEVICE CATEGORY | MD 1302 - Monitoring devices of vital physiological parameters |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | <p>SHENZHEN AEON TECHNOLOGY A300 AND A330 PULSE OXIMETER ARE FINGERTIP PULSE OXIMETER, BASED ON ALL DIGITAL TECHNOLOGY, IS INTENDED FOR NON-INVASIVE SPOT-CHECK MEASUREMENT OF SPO₂ AND PULSE RATE. THE PRODUCT IS SUITABLE FOR USE IN FAMILY, HOSPITAL (INCLUDING CLINICAL USE IN INTERNIST/SURGERY, ANESTHESIA, PEDIATRICS, INTENSIVE CARE AND ETC.), OXYGEN BAR, SOCIAL MEDICAL ORGANIZATIONS AND PHYSICAL CARE IN SPORTS. SHENZHEN AEON TECHNOLOGY A360 PULSE OXIMETER IS A NON-INVASIVE, HANDHELD PATIENT OXIMETER. IT OPERATES ON ALKALINE OR RECHARGEABLE BATTERY POWER SUPPLY. IT IS COMPACT, SMALL, LIGHT, AND EASY FOR LEARNING AND HANDLING. IT IS SUITABLE FOR MONITORING ADULT AND CHILD PATIENTS. IT IS WIDELY USED IN THE HOSPITAL'S OPERATION ROOM, ICU, CLINIC SECTION OFFICE, OUT-PATIENT DEPARTMENT, SICKROOM, EMERGENCY TREATMENT, AND THE RECOVERY AND HEALTH CARE ORGANIZATIONS, OR IN THE FAMILY NURSING AND IN THE PROCESS OF TRANSPORTING PATIENTS.</p> |
| DEVICE INTENDED PURPOSE | <p>SHENZHEN AEON TECHNOLOGY PULSE OXIMETER IS A DEVICE INTENDED FOR TRANSCUTANEOUS MEASUREMENT OF OXYGEN SATURATION (SPO₂) IN THE BLOOD USING LIGHT DETECTION THROUGH A SENSOR. THE LIGHT PRODUCED ILLUMINATES ARTERIAL TISSUE BLOOD, IS RECEIVED BY A DETECTOR AND MEASURED USING THE PRINCIPLE OF SPECTROPHOTOMETRY.</p> |
| VALIDITY DATE OF REGISTRATION | 28/12/2017 - 27/12/2022 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
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| 1 | A300 Fingertip Pulse Oximeter | A300 |
| 2 | A330 Fingertip Pulse Oximeter | A330 |
| 3 | A360 Handheld Pulse Oximeter | A360 |



MEDICAL DEVICE AUTHORITY