



DEVICE DETAILS

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
1	A300 Fingertip Pulse Oximeter	A300
2	A330 Fingertip Pulse Oximeter	A330
3	A360 Handheld Pulse Oximeter	A360



MEDICAL DEVICE AUTHORITY