



DEVICE DETAILS

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| NAME OF DEVICE | BT-710 PULSE OXIMETER |
| ESTABLISHMENT NAME | TEEPHAM MEDICAL SDN. BHD. |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GC2518124-192696 |
| BRAND NAME | BISTOS |
| MEDICAL DEVICE CATEGORY | MD 1302 - Monitoring devices of vital physiological parameters |
| DEVICE GROUPING TYPE | SYSTEM |
| DEVICE DESCRIPTION | The BT-710 Pulse Oximeter is a hand held oximeter, provides patient vital signs such as pulse rate, blood oxygen saturation and perfusion index by placing the sensors to the appropriate site of patient. The device is composed with display, control circuit and panel, and input part for SpO2 sensors. It detects SpO2 and PR using specific sensors. The detected analog signal amplified and converted to digital. This converted data feed to the CPU and converted to the display format as number and waveform. This device is incorporated with alarm system. The alarm generated when the detected signal range is beyond the user set alarm limits. |
| DEVICE INTENDED PURPOSE | The Bistos BT-710 Pulse Oximeter acquire the blood oxygen saturation (SpO2) and pulse rate (PR). The signals are converted into digital data and processed, examines the data for alarm conditions and display the data. The pulse oximeter also provides operating control for the user. The pulse oximeter intend to use in hospital clinical area such as general ward, to provide additional information to the medical and nursing staff about the blood oxygen saturation of the patient. The BT-710 Pulse Oximeters are intended to be used only under regular supervision of clinical personnel. It is suitable for adult, pediatric and neonate. The intended locations of use are hospitals and clinics. 1) Intended patient population - Adult (>18 years adults), Pediatrics (30 days < and <18 years) and Neonate (0 days< and < 30 days) 2) Intended user profile - Doctor, physicians or nursing staff who is qualified personnel - Basic experiences or knowledge on medical field, especially on patient monitoring - Trained or requested to read IFU before use 3) Environment of use - Hospital and clinic - Requirements: Stable power source 4) Scope of application This pulse oximeter is suitable for bedside monitoring of patient. This pulse oximeter enables the monitoring of blood oxygen saturation (SpO2) and pulse rate (PR). It is equipped with a replaceable built-in battery to provide convenience for the patient movement in hospital. |
| VALIDITY DATE OF REGISTRATION | 27/12/2024 - 26/12/2029 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
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| 1 | Pulse Oximeter | BT-710 |
| 2 | Reusable Adult Finger Clip SpO2 Sensor | U403-01 |
| 3 | Reusable Pediatric Finger Clip SpO2 Sensor | U103-01 |
| 4 | Reusable Neonate Wrap SpO2 Sensor | U303-01 |
| 5 | AC/DC Adapter | UE10WCPI-050200SPA |



MEDICAL DEVICE AUTHORITY