



DEVICE DETAILS

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| NAME OF DEVICE | PULSE OXIMETER |
| ESTABLISHMENT NAME | BION MEDICAL SDN BHD |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GB3492221-65288 |
| BRAND NAME | BION |
| MEDICAL DEVICE CATEGORY | MD 1100 - GENERAL ACTIVE MEDICAL DEVICES |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | The pulse oximeter is used to measure arterial oxygen saturation (% SpO ₂), the percentage of oxyhemoglobin (HbO ₂) relative to the total hemoglobin (Hb). It also measures the pulse rate (PR, the number of pulse beats per minute), and gives the perfusion index, an indication of pulse strength at the monitoring site. |
| DEVICE INTENDED PURPOSE | The pulse oximeter uses the non-invasive optical transmittance method to measure arterial oxygen saturation and pulse rate. Do not use it for continuous care for patients. |
| VALIDITY DATE OF REGISTRATION | 18/06/2021 - 17/06/2026 |

LIST OF DEVICE



| NO | NAME OF DEVICE | IDENTIFIER |
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| 1 | FingerTip Pulse Oximeter | P100 |
| 2 | FingerTip Pulse Oximeter with Blue tooth | P100BT |