

DEVICE DETAILS

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| NAME OF DEVICE | PULSE OXIMETER |
| ESTABLISHMENT NAME | ONEWORLD CORPORATE (M) SDN. BHD. |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE |
| REGISTRATION NO | GC7968521-77190 |
| BRAND NAME | SURGIPLUS/M70C |
| MEDICAL DEVICE CATEGORY | MD 1302 - Monitoring devices of vital physiological parameters |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | The pulse oximeter provides a non-invasive measurement of the arterial oxygen saturation (SpO2) and the heart rate (pulse rate). Oxygen saturation indicates the percentage of haemoglobin in arterial blood that is loaded with oxygen. Oximeters work by the principles of spectrophotometry: the relative absorption of red (absorbed by deoxygenated blood) and infrared (absorbed by oxygenated blood) light of the systolic component of the absorption waveform correlates to arterial blood oxygen saturation. |
| DEVICE INTENDED PURPOSE | The pulse oximeter provides a non-invasive measurement of the arterial oxygen saturation (SpO2) and the heart rate (pulse rate) |
| VALIDITY DATE OF REGISTRATION | 01/11/2021 - 31/10/2026 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
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| 1 | PULSE OXIMETER | 9550201308180 |
| 2 | PULSE OXIMETER | 9550201308180-1 |
| 3 | PULSE OXIMETER | 9550201308180-2 |