



DEVICE DETAILS

| | |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NAME OF DEVICE | FINGERTIP PULSE OXIMETER |
| ESTABLISHMENT NAME | REVO HEALTHCARE SDN BHD |
| ROLE OF ESTABLISHMENT | MANUFACTURER |
| REGISTRATION NO | GC7466321-75426 |
| BRAND NAME | NOVOPLUS |
| MEDICAL DEVICE CATEGORY | MD 1302 - Monitoring devices of vital physiological parameters |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | The Fingertip Pulse Oximeter PO99B and PO99C are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches to 0.9 inches) and for patients during no-motion condition. Both of PO99B and PO99C are as a stand-only device for multiple uses with 1 AAA Alkaline battery. It includes an OLED display screen and a warning or indicator function for abnormal readings. Both PO99B and PO99C perform their measurement by using dual wavelength LED at 660 nanometers and 880 nanometers. However, these two models are using different types of input keys for the device setting. The PO99B has a 5-directional key for setting while the PO99C has a push-down input key for screen rotation and device setting. |
| DEVICE INTENDED PURPOSE | The Fingertip Pulse Oximeter is intended for measuring functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0,3 inches ~0,9 inches) and for patients during no-motion condition. |
| VALIDITY DATE OF REGISTRATION | 08/10/2021 - 07/10/2026 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|--------------------------|------------|
| 1 | FINGERTIP PULSE OXIMETER | PO99B |
| 2 | FINGERTIP PULSE OXIMETER | PO99C |