



## DEVICE DETAILS

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|-------------------------------|--|
| NAME OF DEVICE                | WRISTOX2® PULSE OXIMETER   |
| ESTABLISHMENT NAME            | ACUCARE SYSTEMS (M) SDN BHD  |
| ROLE OF ESTABLISHMENT         | AUTHORIZED REPRESENTATIVE  |
| REGISTRATION NO               | GC7541819-36841  |
| BRAND NAME                    | NONIN WRISTOX2®  |
| MEDICAL DEVICE CATEGORY       | MD 1300 - MONITORING DEVICES   |
| DEVICE GROUPING TYPE          | FAMILY   |
| DEVICE DESCRIPTION            | The Model 3150 is a pulse oximeters with memory for patient data collection and Bluetooth communication capability. The Model 3150 with the use of an external sensor (with a specific cable connection and optional interface cable for Nonin standard sensors) measures the patient's %SpO2 and pulse rate. The unit is small and light weight allowing it to be worn by the patient (wrist, upper arm, infant's thigh or bed rail) with the use of an adjustable strap.   |
| DEVICE INTENDED PURPOSE       | The Nonin Model 3150, WristOx2 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring, displaying and storing functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. It is intended for spot-checking and/or data collection and recording of adult and pediatric patients, during both no motion and motion conditions, and for patients who are well or poorly perfused. The intended use environments are hospitals, medical facilities, ambulatory, subacute, and sleep study environments and mobile units. |
| VALIDITY DATE OF REGISTRATION | 28/11/2019 - 27/11/2024  |

## LIST OF DEVICE

| NO | NAME OF DEVICE                          | IDENTIFIER |
|----|---|------------|
| 1  | WristOx2 Model 3150 with USB            | 3150 USB   |
| 2  | WristOx2 Model 3150 with BLE            | 3150 BLE   |
| 3  | Fingerclip Sensor Adult, for WristOx    | 8000AA-WO2 |
| 4  | Reusable Flex Snsor for WristOx2, Adult | 8000J-WO2  |
| 5  | Soft Sensor Small for 3150 WristOx2     | 8000SS-WO2 |
| 6  | Soft Sensor Medium for 3150 WristOx2    | 8000SM-WO2 |
| 7  | Soft Sensor Large for 3150 WristOx2     | 8000SL-WO2 |
| 8  | Adapter Cable for WristOx2              | 3150I      |

| NO | NAME OF DEVICE                                      | IDENTIFIER |
|----|---|------------|
| 9  | Model 8000AA FINGER CLIP SENSOR                     | 8000AA     |
| 10 | Model 8000AP PED FINGER CLIP SENSOR                 | 8000AP     |
| 11 | Model 8000Q2 EAR CLIP SNSR                          | 8000Q2     |
| 12 | MODEL 8000R REFLECTANCE SNSR                        | 8000R      |
| 13 | Forehead reflectance sensor holder for 8000R Sensor | 8000H      |
| 14 | MODEL 8000SS SOFT SENSOR SMALL                      | 8000SS     |
| 15 | MODEL 8000SM SOFT SENSOR MEDIUM                     | 8000SM     |
| 16 | MODEL 8000SL SOFR SENSOR LARGE                      | 8000SL     |
| 17 | Adult Reusable Flex SpO2 sensors with FlexiWrap     | 8000J      |
| 18 | Flexiwrap, Adult                                    | 8000JFW    |
| 19 | 6000CA SENSORS CLOTH ADULT 24CT                     | 6000CA     |
| 20 | 6000CP SENSOR CLOTH PED 24CT                        | 6000CP     |
| 21 | 6000CI SNSR CLOTH INFANT 24CT                       | 6000CI     |
| 22 | Model 7000A Flexi-Form III Disposable Sensor        | 7000A      |
| 23 | Model 7000P Flexi-Form III Disposable Sensor        | 7000P      |
| 24 | Model 7000I Flexi-Form III Disposable Sensor        | 7000I      |
| 25 | 6500MA Standard Disposable Durafoam Sensor          | 6500MA     |
| 26 | 6500SA Small Disposable Durafoam Sensor             | 6500SA     |
| 27 | Carrying Case                                       | 3100CC     |
| 28 | PC USB Interface Cable                              | 3150SC     |
| 29 | Adjustable Wrist Stap for WO2                       | 3150WB     |
| 30 | Wrist Band Extender                                 | 3100WBE    |
| 31 | nVISION Software for Microsoft Windows              | nVISION    |