




DEVICE DETAILS

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