



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	NONIN ONYX FINGER PULSE OXIMETER
<b>ESTABLISHMENT NAME</b>	ACUCARE SYSTEMS (M) SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GC8563126-231427
<b>BRAND NAME</b>	NONIN
<b>MEDICAL DEVICE CATEGORY</b>	MD 1300 - MONITORING DEVICES
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	<p>Nonin Medical's finger pulse oximeters are small lightweight portable devices that display numerical values for functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate. Light emitting diodes (LEDs) are contained within the sensor along with the photo detector, which is on the opposite side of the probe from LEDs. The SpO<sub>2</sub> and heart rate are shown on the LED digital displays contained within the finger oximeter. A tricolor LED display provides a visual indicator of the pulse signal quality, while flashing the corresponding pulse rate. This display changes color to alert the user to changes in pulse quality that may affect the readings: green indicates good pulse quality, yellow indicated a marginal pulse quality and red indicates an inadequate pulse signal. The electronics and microprocessor are housed in the sensor, which is activated by inserting a patient's finger into the oximeter. This activates the power to the internal circuitry. The device is intended for spot-checking adult and pediatric patients who are well or poorly perfused. The Oxyx® II, Model 9550 and Model 9590 devices are all powered by 2 1.5 volt AAA-size disposable alkaline batteries. Models 9550 and 9590 provide 36 hours of operation while Model 9590 will provide approximately 600 spot checks. All require no calibration or maintenance other than battery replacement.</p>
<b>DEVICE INTENDED PURPOSE</b>	<p>The Nonin® Onyx II Model 9550 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO<sub>2</sub>) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services. The Nonin® Onyx Vantage 9590 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO<sub>2</sub>) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on digits (fingers, thumb, toes) that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.</p>

<b>VALIDITY DATE OF REGISTRATION</b>	23/04/2026 - 22/04/2031
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## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		



**MEDICAL DEVICE AUTHORITY**