



DEVICE DETAILS

NAME OF DEVICE	NONIN ONYX VANTAGE FINGER PULSE OXIMETER
ESTABLISHMENT NAME	ACUCARE SYSTEMS (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC11120720-38475
BRAND NAME	NONIN
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Nonin Medical's finger pulse oximeters are small lightweight portable devices that display numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse 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.
DEVICE INTENDED PURPOSE	The Nonin Finger Pulse Oximeter is a small, lightweight portable device intended for used in measuring and displaying functional hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused.
VALIDITY DATE OF REGISTRATION	06/01/2020 - 05/01/2025

LIST OF DEVICE



NO	NAME OF DEVICE	IDENTIFIER
1	Onyx II 9550 Pulse Oximeter	9550
2	Onyx Vantage 9590 Pulse Oximeter	9590
3	Onyx3 9591 Finger Pulse Oximeter	9591
4	9500CC- Carrying Case, Black	2003-102
5	9590 Lanyard	6918-000
6	Retractable Lanyard	6919-002
7	Fingertip Carrying Case	5097-000
8	Protective Carrying Case	3802-000
9	Fingertip Lanyard	5096-000