



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	BRAVOMED SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC2776521-81598
BRAND NAME	BRAVOMED
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>Bravomed Fingertip Pulse Oximeter is intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR). The Fingertip Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 905 nm, which is Infrared light. Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO₂. The Pulse Oximeter is powered by 2 AAA alkaline batteries. The device mainly composed of PCB board, On/Off button, mode button, OLED or LED screen, battery compartment, and plastic shell. The device is a spot-check pulse oximeter and does not include alarms. The device is not intended for life supporting or life-sustaining.</p>
DEVICE INTENDED PURPOSE	<p>Bravomed Fingertip Pulse Oximeter is intended is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environment.</p>
VALIDITY DATE OF REGISTRATION	21/12/2021 - 20/12/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Pulse Oximeter	Bravomed/ B'Oxi 1
2	Fingertip Pulse Oximeter	Bravomed/ B'Oxi 2