



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	AA ALIVE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB6914321-77538
BRAND NAME	FINGERTIP PULSE OXIMETER
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>An oximeter is an active device that measures arterial oxygen saturation and pulse rate. An oximeter can handheld or put measure at fingertip, powered by batteries. There are two types of oximeter: hospital grade handheld oximeter and personal use fingertip pulse oximeter. Hospital grade is handheld and intended for all ages of users and for continuous monitoring. Personal use oximeters are smaller and generally intended for spot-checking of arterial oxygen saturation and pulse rate. Fingertip Pulse Oximeters are small and compact device which user put their finger in between the device. This noninvasive tool attaches painlessly to user fingertip, sending two wavelengths of light through the finger to measure pulse rate and oxygen saturation. Fingertip Pulse Oximeters are ideal for spot-checking of oxygen saturation and pulse rate. Fingertip pulse oximeter is portable. The readings will be displayed on the OLED screen. Some manufactures have battery packs. No accessory is required for this pulse oximeter. Fingertip pulse oximeter is normally bought at retail pharmacy. A short briefing/explanation from pharmacist is sufficient for user to operate the fingertip oximeter. The fingertip pulse oximeter is intended for use in measuring and displaying functional oxygen saturation of arterial haemoglobin (%SpO₂) and pulse rate (PR). The device measures SpO₂ and PR with a SpO₂ sensor and displays on the OLED after certain further processing. It is hence used to "spot check" human Haemoglobin saturation and heart rate through finger, NOT for continuous monitoring. The product does not have therapeutically effect. The device only contacts with skin (uninjured). There are two types of fingertip pulse oximeter, which is C101A2 & C101A3.</p>
DEVICE INTENDED PURPOSE	<p>The fingertip pulse oximeter is intended for use in measuring and displaying functional oxygen saturation of arterial haemoglobin (%SpO₂) and pulse rate (PR). The device measures SpO₂ and PR with a SpO₂ sensor and displays on the OLED after certain further processing. It is used to "spot check" human Haemoglobin saturation and heart rate through finger, NOT for continuous monitoring. The product does not have therapeutically effect. The device only contacts with skin (uninjured). There are two types of fingertip pulse oximeter, which is C101A2 and C101A3.</p>
VALIDITY DATE OF REGISTRATION	11/11/2021 - 10/11/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Pulse Oximeter C101A3	C101A3
2	Fingertip Pulse Oximeter C101A2	C101A2

