

DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	FELCO MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC2231721-73320
BRAND NAME	HEARTCARE
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The product is mainly indicated for measurement of human Oxygen Saturation (SpO ₂), Pulse Rate (PR) and PI (Perfusion Index). The product has visual prompts and verbal prompts (optional), such as finger out and pulse sound (optional). The applied part of this device is silicone sleeve. The measuring principles of pulse oximeter is based on Lambert-Beer law, the spectrum absorption characteristics is different of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO ₂) in red light and near-infrared light zones. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO ₂) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse.
DEVICE INTENDED PURPOSE	Fingertip pulse oximeter is intended for noninvasive measurement of oxygen saturation, pulse rate and perfusion index in homecare and hospitals, applicable for children and adult.
VALIDITY DATE OF REGISTRATION	23/09/2021 - 22/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Pulse Oxymeter	LOX100A
2	Fingertip Pulse Oxymeter	LOX100B
3	Fingertip Pulse Oxymeter	LOX100C
4	Fingertip Pulse Oxymeter	LOX100D