



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	ONECARE BIOTECH SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC3880222-83400
BRAND NAME	LEPU
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The product is mainly indicated for measurement of human Oxygen Saturation (SpO2), Pulse Rate (PR) and PI(Perfusion Index). The product has visual prompts and verbal prompts , such as finger out and pulse sound (optional). The applied part of this device is silica gel pad. The measuring principles of pulse oximeter is based on Lambert Beer law, The spectrum absorption characteristics is different of Reductive hemoglobin(RHb) and Oxyhemoglobin(Hbo2) in red light and nearinfrared light zones. The pulse oximeter calculate Spo2 ,PR and PI from the light intensity absorption difference by measuring the ratio of absorbed red and infrared light with each pulse.
DEVICE INTENDED PURPOSE	The LOX100 Fingertip Oximeter is intended for use in homes or hospitals for noninvasive measurement of oxygen saturation, pulse rate and perfusion index. The device can be used for both children and adults. This device is intended only for spotchecking.
VALIDITY DATE OF REGISTRATION	16/01/2022 - 15/01/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Pulse Oxymeter (Blue)	LOX100A
2	Fingertip Pulse Oxymeter (Green)	LOX100B
3	Fingertip Pulse Oxymeter (Cyan)	LOX100C
4	Fingertip Pulse Oxymeter (Yellow)	LOX100D