



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP OXIMETER
ESTABLISHMENT NAME	LEPU COMMERCE(MALAYSIA) SDN.BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC4510324-176072
BRAND NAME	LEPU MEDICAL
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>This Fingertip Oximeter is intended to measure pulse rate and functional oxygen saturation (SpO2) through a patient's finger. It is applicable for spot-checking the SpO2 and pulse rate of adult and paediatric patients in homes and medical clinics. Models with external sensor options and over-limit Indication may be used for longer periods of time dependent on the suitability of the sensor selected. This device measures SpO2, Pulse Rate and PI, displays Pulse bar and Plethysmogram. It comes in three models, three colours PC-60NW(red), PC-60FW (blue) and PC-60E (orange). PC-60NW ● Applicable to adult, pediatric and neonate with external probe ● Color Display with Automatic rotation in 4 directions ● Measuring SpO2, Pulse Rate and PI, display Pulse bar and Plethysmogram. ● Wireless module with APP for real-time display ● Artifact removal and anti-motion ● Splash-proof and Drop-resistant ● Audible and visual alarm with low battery indication ● Automatic Power on/off PC-60FW ● OLED Display with 4 - way rotation ● Measure SpO2, Pulse Rate and PI, display Pulse bar and Plethysmogram. ● Spot-check and continuous monitoring mode • Pulse rate analysis on spot check mode ● Voice broadcast for measurement results ● Store up to 12 sets of unit results ● Wireless Module with App for real-time display ● Artifact removal and anti-motion ● Splash -proof and Drop-resistant ● Audible and visual alarm with low battery indication ● Automatic Power on/off PC-60E ● Applicable to adult, pediatric and neonate with external probe ● Color display with automatic rotation in 4 directions ● Measure Spo2, Pulse Rate and PI display ● Pulse bar and Plethysmogram. ● Artifact removal and anti-motion ● Splash-proof and Drop-resistant ● Audible and visual alarm with low battery indication ● Automatic Power on/off</p>
DEVICE INTENDED PURPOSE	<p>This Fingertip Oximeter is intended to measure pulse rate and functional oxygen saturation (SpO2) through a patient's finger. It is applicable for spot-checking the SpO2 and pulse rates of adult and paediatric patients in homes and medical clinics. Models with external sensor options and over-limit Indication may be used for longer periods of time dependent on the suitability of the sensor selected.</p>
VALIDITY DATE OF REGISTRATION	03/07/2024 - 02/07/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Oximeter	PC-60NW

NO	NAME OF DEVICE	IDENTIFIER
2	Fingertip Oximeter	PC-60FW
3	Fingertip Oximeter	PC-60E
4	Accessories	(not set)
5	Batteries	LARQE
6	Pouch	70mm*120mm
7	Lanyard	PC-60
8	External SpO2 probe	KRK272

