



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).</p> <ul style="list-style-type: none"> ● 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
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
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



MEDICAL DEVICE AUTHORITY