



DEVICE DETAILS

NAME OF DEVICE	HANDHELD PULSE OXIMETER (PC-66B)
ESTABLISHMENT NAME	LEPU COMMERCE(MALAYSIA) SDN.BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC4172524-175148
BRAND NAME	LEPU MEDICAL
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>The pulse oximeter provides a non-invasive measurement of the arterial oxygen saturation (SpO₂) and the heart rate (pulse rate). Oxygen saturation indicates the percentage of haemoglobin in arterial blood that is loaded with oxygen. Therefore, it is an important parameter for assessing respiratory function.</p> <ul style="list-style-type: none">● 22-inch TFT display for SpO₂, PI, Plethysmogram, PR● MoveOxy SpO₂ technology with artefact removal and anti-motion performance● Various SpO probes for Adult, Paediatric, and Neonate● Inbuilt lithium battery for continuous monitoring● Up to 384 hours SpO₂ data storage for reviewing● Adjustable alarm limit, pitch tone level, and key tone
DEVICE INTENDED PURPOSE	<p>This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate and functional oxygen saturation (SpO₂). It is applicable for monitoring SpO₂ and pulse rate of adult and paediatric patients in clinical institutions and homes.</p>
VALIDITY DATE OF REGISTRATION	25/06/2024 - 24/06/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	HANDHELD PULSE OXIMETER	PC-66B
2	ACCESSORIES	(not set)
3	SpO ₂ probe	KS-C01
4	Holder	KRK112
5	Battery	LARQE
6	Charging cable	LXCP12-005
7	Data cable	USB-A