



DEVICE DETAILS

NAME OF DEVICE	HANDHELD PULSE OXIMETER (SP-20)
ESTABLISHMENT NAME	LEPU COMMERCE(MALAYSIA) SDN.BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC4638724-178881
BRAND NAME	LEPU MEDICAL
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO₂), and temperature (optional). It is applicable for detecting SpO₂, pulse rate, and temperature of adult and neonate patients in clinical institutions and homes. ● It is applicable for adults, paediatric, and neonate measurements in hospital and home. ● Measuring SpO₂, Pulse Rate and Temperature (optional) ● 3.5-inch TFT display of PI%, plethysmograph and pulse bar ● 16 user IDs for marking data and can be added ● A built-on holder for convenient standing on desktop ● The base is used to hold the oximeter, and also for charging. ● Lithium battery up to 18 hours ● More than 500 hours SpO₂ and PR data storage ● PC software for data management. ● Audible and visual alert function is available ● Auto power off is available</p>
DEVICE INTENDED PURPOSE	<p>This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO₂), and temperature (optional). It is applicable for detecting SpO₂, pulse rate, and temperature of adult and neonate patients in clinical institutions and homes.</p>
VALIDITY DATE OF REGISTRATION	08/08/2024 - 07/08/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Handheld Pulse Oximeter	SP-20
2	SpO ₂ probe	KS-AC01
3	SpO ₂ probe	KS-AR02
4	SpO ₂ probe	KS-AYW02
5	SpO ₂ probe	KS-ALW025
6	SpO ₂ probe	Analog Y-Type
7	SpO ₂ probe	Analog D-Type

NO	NAME OF DEVICE	IDENTIFIER
8	Oximeter rubber cover	KRK315
9	Charging base	LXCP12-005
10	Temperature probe	KT-602
11	Charging cable	USB-A
12	USB data cable	USB-A

