



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	HANDHELD PULSE OXIMETER (SP-20)
<b>ESTABLISHMENT NAME</b>	LEPU COMMERCE(MALAYSIA) SDN.BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GC4638724-178881
<b>BRAND NAME</b>	LEPU MEDICAL
<b>MEDICAL DEVICE CATEGORY</b>	MD 1302 - Monitoring devices of vital physiological parameters
<b>DEVICE GROUPING TYPE</b>	SYSTEM
<b>DEVICE DESCRIPTION</b>	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
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	08/08/2024 - 07/08/2029

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Handheld Pulse Oximeter	SP-20
2	SpO2 probe	KS-AC01
3	SpO2 probe	KS-AR02
4	SpO2 probe	KS-AYW02
5	SpO2 probe	KS-ALW025
6	SpO2 probe	Analog Y-Type

<b>NO</b>	<b>NAME OF DEVICE</b>	<b>IDENTIFIER</b>
7	SpO2 probe	Analog D-Type
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



**MEDICAL DEVICE AUTHORITY**