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	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 Sp02, 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 Sp02 and PR data storage ● PC software for data management. ● Audible and visual alert function is available ● Auto power off is available
DEVICE INTENDED PURPOSE	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.
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	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
7	SpO2 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