Medical Device Authority Malaysia

Public Search

Malaysia Medical Device Register (MMDR)

DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER (PF-10AW,PF-10AW1,PF-10A,PF-10A1, PF-10BW, PF-10BW1?PF-10B,PF-10B1)
ESTABLISHMENT NAME	LEPU COMMERCE(MALAYSIA) SDN.BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10766524-191958
BRAND NAME	LEPU MEDICAL
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The pulse oxygen saturation, the percentage of HbO2 in the total Hb in the blood, namely the so-called O2 concentration in the blood, is an important bio-parameter for the respiration. The intergradations of oxygen molecule in the blood and hemoglobin in erythrocyte are reversible. Hemoglobins integrated with oxygen are called HbO2, and those released O2 are called HbR. Oxyhemoglobin and deoxyhemoglobin (HHb) absorb red Marginal and infrared of specific wavelength, thus the Marginal of the two wavelengths emitted from SpO2 sensor is absorbed when it passes through the finger, and approximate pulse oxygen saturation is calculated by measuring absorption of the Marginal. The device is a lightweight, portable health wrist oximeter for use in the home or in healthcare facilities. SpO2 measurement technology is based on developed photoelectron method, the circuit design and calculation software was developed by Shenzhen Viatom Technology Co., Ltd. The SpO2 sensor receives the optical signal from the red light and infra-red light through the finger. Insert the finger into the oximeter, there are two emitting tube (red light diodes and infrared diodes) located on the inner upside of the sensor and they can emit red light and infrared; There is the receiving end located on the inner downside of the sensor, and it can transmit the red light and infrared into the pulse signal through finger. The MCU receives the pulse signal, gets the frequency signal by counting, processes its digital signal, and finally gets the measured SpO2 value. The PR is averagely calculated by above peak intervals of PR waveform. The device is powered by internal battery. The device is not for life-supporting or lifesustaining, not for implant. The device or sensor is not sterile and the sensor does not need sterilization and the sensor is reusable but does not need re-sterilization since it is not sterile. The device is for prescription. The device does not contain drug or biological products. The device consist of main unit, SpO2 sensor, wristband and charging cable. The main unit is mainly composed of MCU (built-in Bluetooth module), Power circuit, SpO2 measurement circuit, Display control circuit, etc. that is an integrated product with modular design
DEVICE INTENDED PURPOSE	This Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through a patient's finger. It is applicable for spot-checking SpO2 and pulse rate of adult and pediatric patients in homes and medical clinics.
VALIDITY DATE OF REGISTRATION	15/12/2024 - 14/12/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	PF?10AW
2	Pulse Oximeter	PF?10AW1
3	Pulse Oximeter	PF?10A
4	Pulse Oximeter	PF?10A1
5	Pulse Oximeter	PF?10BW
6	Pulse Oximeter	PF?10BW1
7	Pulse Oximeter	PF?10B
8	Pulse Oximeter	PF?10B1