



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	MEDIEN SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10621625-207442
BRAND NAME	WELLUE
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	The pulse oxygen saturation, the percentage of HbO ₂ in the total Hb in the blood, namely the so-called O ₂ 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 HbO ₂ , and those released O ₂ are called HbR. Oxyhemoglobin and deoxyhemoglobin (HHb) absorb red Marginal and infrared of specific wavelength, thus the Marginal of the two wavelengths emitted from SpO ₂ sensor is absorbed when it passes through the finger, and approximate pulse oxygen saturation is calculated by measuring absorption of the Marginal.
DEVICE INTENDED PURPOSE	This Pulse Oximeter is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO ₂), pulse rate of adults in home or healthcare facilities environment.
VALIDITY DATE OF REGISTRATION	12/07/2025 - 11/07/2030



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PULSE OXIMETER	PO2