

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 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.	
DEVICE INTENDED PURPOSE	This Pulse Oximeter is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO2), 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	