



## DEVICE DETAILS

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

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PULSE OXIMETER	PO2