



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	RESETT SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7610823-132933
BRAND NAME	ACCURATE
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	The pulse oximeter can monitor significant vital sign parameters of patients, including SpO2 and Pulse. It senses arterial oxygen saturation physiological change with sensor and converses it to electric signal. Then, the data are calculated and analyzed by data analysis software and displayed on LCD.
DEVICE INTENDED PURPOSE	The Pulse Oximeter is a portable, convenient, non-invasive device, used for monitor arterial hemoglobin oxygen saturation (SpO2) and pulse rate. The personal application are adult patients (weight: >30kgs) and pediatric patients (weight: 20-30kgs). We recommend index finger, middle finger and ring finger are suitable position for monitor. It's intended for spot-checking or attended-care monitoring in Home Health Care and Medical Facility.
VALIDITY DATE OF REGISTRATION	26/05/2023 - 25/05/2028



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PULSE OXIMETER	6927394500210