



## DEVICE DETAILS

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| <b>NAME OF DEVICE</b>                | PULSE OXIMETER   |
| <b>ESTABLISHMENT NAME</b>            | RESETT SDN. BHD.   |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE  |
| <b>REGISTRATION NO</b>               | GB7610823-132933   |
| <b>BRAND NAME</b>                    | ACCURATE   |
| <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 oximeter can monitor significant vital sign parameters of patients, including SpO2 and Pulse. It senses arterial oxygen saturation physiological change with sensor and converts it to electric signal. Then, the data are calculated and analyzed by data analysis software and displayed on LCD.   |
| <b>DEVICE INTENDED PURPOSE</b>       | 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. |
| <b>VALIDITY DATE OF REGISTRATION</b> | 26/05/2023 - 25/05/2028  |

## LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER    |
|----|----------------|---------------|
| 1  | PULSE OXIMETER | 6927394500210 |