

| DEVICE DETAILS | | |
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| NAME OF DEVICE | PULSE OXIMETER | |
| ESTABLISHMENT NAME | QUANTUM UPSTREAM SDN.BHD. | |
| ROLE OF ESTABLISHMENT | AUTHORIZED REPRESENTATIVE | |
| REGISTRATION NO | GC10889321-68404 | |
| BRAND NAME | EZYSWISS | |
| MEDICAL DEVICE CATEGORY | MD 1302 - Monitoring devices of vital physiological parameters | |
| DEVICE GROUPING TYPE | SINGLE | |
| DEVICE DESCRIPTION | ezyswiss Pulse Oximeter is intended for non-invasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2). Advanced DSP algorithm can minimize the influence of motion artifact and improve measurement accuracy of low perfusion. The Pulse Oximeter can be used to measure human SpO2 and heart rate through finger. The product is suitable for family, hospital (including clinical use in internist/surgery, Anesthesia, pediatrics etc.) Oxygen Bar, social medical organizations, physical care in sports etc. | |
| DEVICE INTENDED PURPOSE | ezyswiss Pulse Oximeter Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments. | |
| VALIDITY DATE OF REGISTRATION | 03/08/2021 - 02/08/2026 | |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|----------------|------------|
| 1 | PULSE OXIMETER | OXI-01 |