



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 (SpO ₂). 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 SpO ₂ 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 (SpO ₂) 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 |