



## DEVICE DETAILS

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| NAME OF DEVICE                | PULSE OXIMETER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| ESTABLISHMENT NAME            | TEEPHAM MEDICAL SDN. BHD.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| ROLE OF ESTABLISHMENT         | AUTHORIZED REPRESENTATIVE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| REGISTRATION NO               | GB82088101816                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| BRAND NAME                    | CA-MI O2 EASY (REF OX 100000)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| MEDICAL DEVICE CATEGORY       | MD 1300 - MONITORING DEVICES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| DEVICE GROUPING TYPE          | SINGLE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| DEVICE DESCRIPTION            | <p>O2-EASY IS A FINGER PULSE OXIMETER TO CHECK AND MONITOR PATIENT BLOOD-OXYGEN SATURATION (SPO2) LEVEL AND PULSE RATE. ITS SMALL, COMPACT, SIMPLE, RELIABLE AND DURABLE DESIGN GREATLY ENHANCES PATIENT CARE. STANDARD ACCESSORIES INCLUDED: 2 X AAA 1.5V ALKALINE BATTERIES (REPLACEABLE), 1 X HANG LACE. THE CA-MI O2 EASY PULSE OXIMETER IS EASY AND PRACTICAL TO USE. IT IS SMALL, LIGHTWEIGHT AND EASY TO CARRY AROUND. THE DEVICE HAS LOW ENERGY CONSUMPTION AND THE TWO AAA BATTERIES HAVE A LIFE OF 30 HOURS OF CONTINUOUS USE. WHEN THE BATTERY CHARGE IS SO LOW THAT IT MAY AFFECT NORMAL FUNCTIONING OF THE PULSE OXIMETER, A WARNING IS SHOWN ON THE DISPLAY. THE DEVICE AUTOMATICALLY TURNS OFF WHEN IT DOES NOT RECEIVE ANY SIGNALS FOR MORE THAN 8 SECONDS. THE CA-MI O2 EASY PULSE OXIMETER BATTERIES MUST BE REPLACED WHEN THE WARNING LIGHT COMES ON. ITS SURFACES MUST BE CLEANED BEFORE USING IT FOR DIAGNOSIS. THE BATTERIES MUST BE REMOVED FROM THE BATTERY COMPARTMENT IF THE DEVICE IS NOT USED FOR A LONG PERIOD OF TIME. IT IS ADVISABLE TO STORE THE DEVICE AT A TEMPERATURE BETWEEN -20°C~55°C(-4°F~131°F) WITH RELATIVE HUMIDITY &lt;93%. THE DEVICE MUST ALWAYS BE STORED IN A DRY ENVIRONMENT. A HUMID ENVIRONMENT MAY DAMAGE THE DEVICE, REDUCING ITS LIFE.</p> |
| DEVICE INTENDED PURPOSE       | <p>The CA-MI O2 Easy Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients at home (HOME-CARE) or in hospital (including clinical use in surgery, anesthesia, intensive care, etc.). The device is not intended for continuous monitoring. The device is not intended for use during patient transport outside the health facility.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| VALIDITY DATE OF REGISTRATION | 06/12/2021 - 05/12/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|----------------|------------|
| 1  | PULSE OXIMETER | OX 100000  |