



## DEVICE DETAILS

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|--------------------------------------|---|
| <b>NAME OF DEVICE</b>                | TEMP-PULSE OXIMETER   |
| <b>ESTABLISHMENT NAME</b>            | AL GLOBAL CORPORATION (M) SDN BHD   |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE   |
| <b>REGISTRATION NO</b>               | GC10725421-52611  |
| <b>BRAND NAME</b>                    | TEMP-PULSE OXIMETER/MEDLINKET   |
| <b>MEDICAL DEVICE CATEGORY</b>       | MD 1100 - GENERAL ACTIVE MEDICAL DEVICES  |
| <b>DEVICE GROUPING TYPE</b>          | SINGLE  |
| <b>DEVICE DESCRIPTION</b>            | <p>The Pulse Oximeter is intended for continuous use or spot checking in measuring and displaying functional arterial oxygen saturation (SpO<sub>2</sub>), pulse rate and temperature of patients in hospitals, physician's office, clinical settings and home care environment. The Temp-Pulse Oximeter can be used as a oxygen saturation monitor, heart rate monitor, body temperature thermometer and health monitor for home daily use. And also can be a fitness trackers for sportspeople wishing to track their performance and fitness; Recognized Brand and Manufacturer by European Market: MED LINKET produce and export professional medical products to European countries for more than 15 years, and serving local large hospital, medical clinic or facility and healthy community and so on The device contains a dual light source (red LED and infrared red LED) and a photo detector, bone, tissue, pigmentation and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO<sub>2</sub>). Because a measurement Of SpO<sub>2</sub> is dependant on light from the device , excessive ambient light can interfere with this measurement.</p> |
| <b>DEVICE INTENDED PURPOSE</b>       | <p>Shenzhen Med-link Temp Pulse Oximeter is intended for continuous use or spot checking in measuring and displaying functional arterial oxygen saturation (SpO<sub>2</sub>), pulse rate and temperature of patients in hospitals, physician's office, clinical settings and home care environment. Target population: Adult, adolescent and child.</p>   |
| <b>VALIDITY DATE OF REGISTRATION</b> | 18/12/2020 - 17/12/2025   |

## LIST OF DEVICE

| NO | NAME OF DEVICE      | IDENTIFIER |
|----|---------------------|------------|
| 1  | TEMP-PULSE OXIMETER | AM-801     |