



DEVICE DETAILS

NAME OF DEVICE	TEMP-PULSE OXIMETER
ESTABLISHMENT NAME	AL GLOBAL CORPORATION (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC10725421-52611
BRAND NAME	TEMP-PULSE OXIMETER/MEDLINKET
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	<p>The Pulse Oximeter is intended for continuous use or spot checking in measuring and displaying functional arterial oxygen saturation (SpO₂), 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 (SpO₂). Because a measurement Of SpO₂ is dependant on light from the device , excessive ambient light can interfere with this measurement.</p>
DEVICE INTENDED PURPOSE	<p>Shenzhen Med-link Temp Pulse Oximeter is intended for continuous use or spot checking in measuring and displaying functional arterial oxygen saturation (SpO₂), pulse rate and temperature of patients in hospitals, physician's office, clinical settings and home care environment. Target population: Adult, adolescent and child.</p>
VALIDITY DATE OF REGISTRATION	18/12/2020 - 17/12/2025

LIST OF DEVICE

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