



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	PREMIER DIAGNOSTICS SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC5372521-73336
BRAND NAME	CONTEC PULSE OXIMETER
MEDICAL DEVICE CATEGORY	MD 0104 - Non-active medical devices with measuring function
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	<p>The oxygen saturation is the percentage of HbO₂ in the total Hb in the blood, so called the O₂ concentration in blood. It is an important physiological parameter for the respiratory and circulatory system. A number of diseases related to respiratory system may cause the decrease of SpO₂ in the blood, furthermore some other causes such as the malfunction of human body's self adjustment, damages during surgery, and the injuries caused by some medical check up would also lead to the difficulty of oxygen supply in human body and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO₂ is of great help for the doctor to discover the potential danger and is of great important in the clinical medical field. Insert the finger when measuring the device will directly display the SpO₂ value measured, it has a higher accuracy and repeatability.</p>
DEVICE INTENDED PURPOSE	<p>The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO₂) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery , anesthesia, intensive care etc). This device is not intended for continuous monitoring.</p>
VALIDITY DATE OF REGISTRATION	23/09/2021 - 22/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PULSE OXIMETER	CMS50D