

DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	BEST MADE PHARMACEUTICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC1470622-89555
BRAND NAME	BERRY PULSE OXIMETER
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Pulse Oximeter is a common device used to check oxygen saturation (SpO₂) and pulse rate. It is a small, compact, simple, reliable and durable physiological monitoring device suitable for clinical environment, out-patient department and sickroom. It can also be used in the recovery and healthcare organizations as well as the community medical treatments. This product is only intended for adults. Not to be used on children, infant and neonatal. The operating principle is based on light transmission through the hemoglobin. The light transmission of a substance is determined by the Beer-Lambert law, which determines the concentration of a solute (oxyhemoglobin) in a solvent (hemoglobin) can be determined by light absorption. The blood stain depends on the blood oxygen levels, and the blood with high oxygen concentration presents red color due to high concentration of oxyhemoglobin. When the concentration is reduced, the blood takes on a more bluish, due to a greater presence of deoxyhemoglobin (combination of hemoglobin molecules with carbon dioxide). That is, blood is based on spectrophotometry, measuring the amount of light transmitted through the capillaries of the patient, synchronized with the heart pulse. Pulse Oximeter comes with the Bluetooth communication function. It can send data to intelligent terminal and computer.
DEVICE INTENDED PURPOSE	Intended to measure pulse oxygen saturation and pulse rate of adult in clinical environment.
VALIDITY DATE OF REGISTRATION	04/04/2027 - 03/04/2032

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		