



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	KENJO BABY HOUSE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC9955125-194640
BRAND NAME	EMASCARE
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	eMASCARE Fingertip Pulse Oximeter is composed of the main unit, power button and display screen OLED/TFT panel. The Pulse Oximeter is a portable non-invasive device intended for use in measuring and displaying oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate of adults through the finger in hospitals, hospital-type facilities, and home environments. The patient is an intended operator. The Pulse Oximeter use spectrophotometric principles. They transmit two wavelengths of light (660 and 905 nm) through a pulsating vascular bed on the nails and determine oxygen saturation using a variation of the Beer-Lambert law. The relationship between the absorption at the two wavelengths and oxygen saturation determines the calibration curve, which is derived empirically by each manufacturer. The pulse oximeter uses a microprocessor to calculate and display the SPO ₂ from the light absorption data.
DEVICE INTENDED PURPOSE	eMASCARE Fingertip Pulse Oximeter is a portable non-invasive device intended for use in measuring and displaying oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate of adults through the finger in hospitals, hospital-type facilities, and home environments. The patient is an intended operator.
VALIDITY DATE OF REGISTRATION	18/01/2025 - 17/01/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Pulse Oximeter	C101A2 (Black)
2	Fingertip Pulse Oximeter	C101A2 (White)
3	Fingertip Pulse Oximeter	C101H1