



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	FINGERTIP PULSE OXIMETER
<b>ESTABLISHMENT NAME</b>	KENJO BABY HOUSE SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GC9955125-194640
<b>BRAND NAME</b>	EMASCARE
<b>MEDICAL DEVICE CATEGORY</b>	MD 1302 - Monitoring devices of vital physiological parameters
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	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 <sub>2</sub> ) 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 <sub>2</sub> from the light absorption data.
<b>DEVICE INTENDED PURPOSE</b>	eMASCARE Fingertip Pulse Oximeter is a portable non-invasive device intended for use in measuring and displaying oxygen saturation of arterial hemoglobin (SpO <sub>2</sub> ) and pulse rate of adults through the finger in hospitals, hospital-type facilities, and home environments. The patient is an intended operator.
<b>VALIDITY DATE OF REGISTRATION</b>	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