DEVICE DETAILS

NAME OF DEVICE	FINGERTIP OXIMETER PC-60A
ESTABLISHMENT NAME	WI MEDIK SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC8113721-75970
BRAND NAME	CREATIVE MEDICAL
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	The technology of Oximeter is generalization now, and similar devices were appeared in market for many years. We will introduce the working principle roughly as follow: Pulse oximeter uses a light emitter with red and infrared LEDs that shines through a reasonably translucent site with good blood flow. Typical adult/pediatric sites are the finger, toe, pinna (top) or lobe of the ear. Infant sites are the foot or palm of the hand and the big toe or thumb. Opposite the emitter is a photodetector that receives the light that passes through the measuring site. After the transmitted red (R) and infrared (IR) signals pass through the measuring site and are received at the photodetector, the R/IR ratio is calculated. The R/IR is compared to a “look-up” table (made up of empirical formulas) that converts the ratio to a SpO2 value. Most manufacturers have their own look-up tables based on calibration curves derived from healthy subjects at various SpO2 levels.
DEVICE INTENDED PURPOSE	This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through a patient ’s finger. It is applicable for spot-checking SpO 2 and pulse rate of adult and pediatric patients in homes and medical clinics. Models with external sensor options and over-limit Indication may be used for longer periods of time dependent on the suitability of the sensor selected
VALIDITY DATE OF REGISTRATION	08/10/2021 - 07/10/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FINGERTIP OXIMETER PC-60A	PC-60A