



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP OXIMETER
ESTABLISHMENT NAME	EYESMILE CREATIONS SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10977823-150408
BRAND NAME	CREATIVE MEDICAL
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The pulse oxygen saturation (SpO ₂) is the percentage of oxyhemoglobin (HbO ₂) in the total hemoglobin (Hb) in the blood, so-called the O ₂ concentration in the blood. It is an important biological parameter for the respiration. Many of the respiratory disease will cause hypoxemia, even damage the patient's life. As a result, monitoring the SpO ₂ is indispensable in the clinical rescuing. The traditional method to measure SpO ₂ was to take a blood sample from the patient, and then analyzed it by a blood gas analyzer for Partial Pressure of Oxygen, by which SpO ₂ would be calculated. This method is inconvenient and discontinuous. For the purpose of measuring the SpO ₂ more easily and accurately, our company developed the Fingertip Oximeter which can measure the pulse rate simultaneously. The Fingertip Oximeter is small in size, low power consumption, convenient to use and easy to carry. You just need to put a finger into the sensor of the device, the SpO ₂ value will appear in the screen immediately
DEVICE INTENDED PURPOSE	This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO ₂) through patient's finger. It is applicable for spot-checking SpO ₂ and pulse rate of adult and pediatric patients in homes and clinics
VALIDITY DATE OF REGISTRATION	05/10/2023 - 04/10/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PC-60F Fingertip Oximeter	PC-60F
2	PC-60B1 Fingertip Oximeter	PC-60B1
3	PC-60C Fingertip Oximeter	PC-60C
4	PC-60D2 Fingertip Oximeter	PC-60D2
5	PC-60E Fingertip Oximeter	PC-60E

NO	NAME OF DEVICE	IDENTIFIER
6	PC-60NW Fingertip Oximeter	PC-60NW



MEDICAL DEVICE AUTHORITY