

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 (SpO2) is the percentage of oxyhemoglobin (HbO2) in the total hemoglobin (Hb) in the blood, so-called the O2 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 SpO2 is indispensable in the clinical rescuing. The traditional method to measure SpO2 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 SpO2 would be calculated. This method is inconvenient and discontinuous. For the purpose of measuring the SpO2 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 SpO2 value will appear in the screen immediately		
DEVICE INTENDED PURPOSE	This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's finger. It is applicable for spotchecking SpO2 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	
6	PC-60NW Fingertip Oximeter	PC-60NW	