

DEVICE DETAILS			
NAME OF DEVICE	ACULIFE® FINGERTIP PULSE OXIMETER		
ESTABLISHMENT NAME	ACULIFE (M) SDN BHD		
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE		
REGISTRATION NO	GC1534922-89773		
BRAND NAME	ACULIFE		
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES		
DEVICE GROUPING TYPE	SINGLE		
DEVICE DESCRIPTION	Aculife® Fingertip Pulse Oximeter is a non-invasive portable device intended for measuring the level of oxygen saturation (SpO2) and Pulse Rate (PR). It is indicated to be used at home as well as in clinical institutions for the purpose of quick diagnosis on respiratory function of patients. Aculife® Fingertip Pulse Oximeter is suitable to be used on both children and adults. Aculife® Fingertip Pulse Oximeter able to measure SpO2 to indicate the amount of oxygen-carrying haemoglobin in the blood relative to the amount of haemoglobin not carrying oxygen and Pulse Rate to indicate the heart beat per minute. Aculife® Fingertip Pulse Oximeter is a reusable device and is non-sterile. It is small in size, low power consumption, convenient operation and portability. It only required patient to place one finger into fingertip photoelectric sensor for diagnosis, and the display screen will directly show measured value of haemoglobin saturation. It has been proved in clinical experiments that it possesses rather high precision and repeatability.		
DEVICE INTENDED PURPOSE	Intended for measuring the level of oxygen saturation (SpO2) and Pulse Rate.		
VALIDITY DATE OF	01/04/2022 - 31/03/2027		

LIST OF DEVICE			
NO	NAME OF DEVICE	IDENTIFIER	
1	ACULIFE® FINGERTIP PULSE OXIMETER	A3	

01/04/2022 - 31/03/2027

REGISTRATION