



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	CAREFORCE MEDICARE SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC9770721-65290
BRAND NAME	AURELIUS CARE
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>Haemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO₂) that compounded with oxygen and that of all combinativable haemoglobin (Hb) obin (HbO₂) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. It is a very important physiological parameter for Respiratory and Circulation Systems. Many respiratory diseases could reduce haemoglobin saturation in human blood. Moreover, factors such as Automatic Organic Regulation Malfunction caused by anaesthesia, trauma resulted from major operation and some medical examination can also cause problems in oxygen supply, which might reduce human haemoglobin saturation. As a result, such symptoms as megrim, vomiting and asthenia might appear to patients. Hence, it is very important to know hemoglobin saturation of patient timely in clinical medical aspects. The fingertip oximeter features in small volume, low power consumption, convenient operation and portability. It is only necessary for patient to put one finger into fingertip photoelectric sensor for diagnosis, and the display screen will directly show measured value of hemoglobin saturation. It has been proved in clinical experiments that it possesses rather high precision and repeatability.</p>
DEVICE INTENDED PURPOSE	<p>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 SpO₂ 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.</p>
VALIDITY DATE OF REGISTRATION	28/06/2021 - 27/06/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Pulse Oximeter	APO-20
2	Fingertip Pulse Oximeter	APO-20A
3	Fingertip Pulse Oximeter	APO-20C

NO	NAME OF DEVICE	IDENTIFIER
4	Fingertip Pulse Oximeter	APO-30
5	Fingertip Pulse Oximeter	APO-30A
6	Fingertip Pulse Oximeter	APO-30C
7	Fingertip Pulse Oximeter	APO-KD1
8	Fingertip Pulse Oximeter	APO-KD2
9	Fingertip Pulse Oximeter	APO-KD3
10	Fingertip Pulse Oximeter	APO-KD8

