DEVICE DETAILS

NAME OF DEVICE	FINGER PULSE OXIMETER
ESTABLISHMENT NAME	GASWORLD SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC7853623-147831
BRAND NAME	ACARE/OXISMARTER 1
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Acare Technology Co., Ltd. Finger type pulse oximeter and handheld type pulse oximeter is intended to measure patient's value of hemoglobin saturation and heartrate. Acare Technology Co., Ltd spo2 probe sensors are intended to be collocated with patient monitor and pulse oximeter for continuous, non-invasive measurement of arterial oxygen saturation. Pulse oximetry is a noninvasive method for accurately estimating oxygen saturation (SaO2) by reading the peripheral oxygen saturation (SpO2). As SaO2 and SpO2 are sufficiently correlated and pulse oximetry has the advantages of being safe, convenient, inexpensive, and noninvasive, this approach is clinically accepted for monitoring oxygen saturation. Pulse oximetry is simple to carry out; it only uses two different light sources and a photodiode. Depending on the measurement site, either the transmissive or the reflective mode can be used. In the transmissive mode, the light sources and photodiode are opposite to each other with the measurement site between them. Light then passes through the site. In the reflective mode, the light sources and photodiode are on the same side, and light is reflected to the photodiode across the measurement site. Currently, the transmissive mode is the most commonly used method because of its high accuracy and stability. Nevertheless, the demand for reflective-mode oximetry is continuously increasing because it does not require a thin measurement site. It can be used at diverse measurement sites such as the feet, forehead, chest, and wrists. In particular, if the wrist is the available measurement site, pulse oximeters can be conveniently used in the form of a band or watch. Haemoglobin Saturation is percentage of Oxyhemoglobin (HbO2) capacity, compounded with oxygen, by all combinativable haemoglobin (Hb) obin (HbO2) capacity in blood. In other words, it is consistence of Oxyhemoglobin in blood. It is a very important ecological parameter for Respiratory circulation System. Many respiratory diseases can result in haemoglobin Saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin saturation might be reduced: Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive Postoperative Trauma, hurts resulted in by some medical examination and etc. In the situation, illnesses, such as light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient's life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time. The Finger type Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a finger type photoelectric sensor for diagnosis, and a display screen will directly show measured value of hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

DEVICE INTENDED PURPOSE	Fingertip Pulse Oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring. The requires no routine calibration or maintenance other than replacement of batteries.
VALIDITY DATE OF REGISTRATION	13/09/2023 - 12/09/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FINGER PULSE OXIMETER	AE-02