



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	IHB HEALTHCARE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC3978321-65258
BRAND NAME	AEON TECHNOLOGY
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>Aeon Technology Pulse Oximeter A30, A310, A310B, A320 and A33 are fingertip pulse oximeter, based on all digital technology, is intended for non-invasive spot-check measurement of SpO2 and pulse rate. The product is suitable for use in family, hospital (including clinical use in internist/surgery, anesthesia, pediatrics, intensive care and etc.), oxygen bar, social medical organizations and physical care in sports. Aeon Technology A36 Pulse Oximeter is a non-invasive, handheld patient Oximeter. It operates on alkaline or rechargeable battery power supply. It is compact, small, light, and easy for learning and handling. It is suitable for monitoring adult and child patients. It is widely used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom, emergency treatment, and the recovery and health care organizations, or in the family nursing and in the process of transporting patients. Parameters measured by the oximeter include: arterial oxygen saturation (SpO2), pulse rate (PR), bar graph and plethysmogram. The oximeter measures these parameters through a SpO2 sensor and displays them on the colour TFT LCD screen after certain further processing. The oximeter is operated and controlled by the buttons on the front panel. It adopts a 2.8 inch colour TFT LCD screen in displaying measurements and in supplementary status indication.</p>
DEVICE INTENDED PURPOSE	<p>Aeon Technology Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments.</p>
VALIDITY DATE OF REGISTRATION	28/06/2021 - 27/06/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	A30
2	Pulse Oximeter	A310
3	Pulse Oximeter	A310B

NO	NAME OF DEVICE	IDENTIFIER
4	Pulse Oximeter	A320
5	Pulse Oximeter	A33



MEDICAL DEVICE AUTHORITY