

DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	CEREMEDIC SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC94689685818
BRAND NAME	GUANGDONG BIOLIGHT MEDITECH CO.,LTD
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>THE BIOLIGHT PULSE OXIMETER MONITOR SIGNIFICANT VITAL SIGN PARAMETERS OF PATIENTS, INCLUDING SPO2 AND PULSE RATE. IT SENSES ARTERIAL OXYGEN SATURATION PHYSIOLOGICAL CHANGE AND CONVERSES IT TO ELECTRIC SIGNAL. THEN, THE DATA ARE CALCULATED AND ANALYZED BY DATA ANALYSIS SOFTWARE AND DISPLAYED ON SCREEN. THE OXIMETER CONTINUOUS OR SPOT CHECK MONITORING OF FUNCTIONAL ARTERIAL OXYGEN SATURATION (SPO2) AND PULSE, AND GIVE OUT ALARM WHEN A CERTAIN PARAMETER EXCEEDS THE DEFAULT LIMIT. THEY ENABLE DOCTORS AND NURSE TO KNOW THE SITUATION OF PATIENTS IN AN ACCURATE AND TIMELY MANNER. THE MEASUREMENT OF OXYGEN SATURATION OF ARTERIAL BLOOD (SPO2) ADOPTS THE PRINCIPLES OF LIGHT SPECTRA AND VOLUME TRACING. THE LED EMITS LIGHTS WITH TWO SPECIFIC WAVELENGTHS, WHICH ARE SELECTIVELY ABSORBED BY OXYHEMOGLOBIN AND DEOXYHEMOGLOBIN. THE PHOTODETECTOR MEASURES. THE CHANGES IN THE LIGHT INTENSITY AFTER THE LIGHT PASSES THE CAPILLARY NETWORK AND ESTIMATES THE RATIO OF OXYHEMOGLOBIN AND THE TOTAL HEMOGLOBIN.</p>
DEVICE INTENDED PURPOSE	<p>THE M70/M70A/M70C PULSE OXIMETER IS INTENDED TO MEASURE FUNCTIONAL ARTERIAL OXYGEN SATURATION (SPO2) AND PULSE RATE OF PATIENTS IN HOSPITAL, HOSPITAL TYPE FACILITIES, AS WELL AS IN THE HOME CARE ENVIRONMENT. THIS OXIMETER IS NOT SUITABLE TO MONITOR PATIENT CONTINUOUSLY FOR LONG TERM. THE M800 PULSE OXIMETER IS INDICATED FOR CONTINUOUS OR SPOT CHECK MONITORING OF FUNCTIONAL ARTERIAL OXYGEN SATURATION (SPO2) AND PULSE RATE OF ADULT, PEDIATRIC AND NEONATAL PATIENTS IN HOSPITAL, HOSPITAL TYPE FACILITIES AS WELL AS IN THE HOME CARE ENVIRONMENT</p>
VALIDITY DATE OF REGISTRATION	07/02/2018 - 06/02/2023

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter M70	M70
2	Pulse Oximeter M70A	M70A
3	Pulse Oximeter M70C	M70C
4	Pulse Oximeter M800	M800



MEDICAL DEVICE AUTHORITY