



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	TEEPHAM MEDICAL SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC4804820-38531
BRAND NAME	BISTOS BT-710 PULSE OXIMETER
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	<p>The BT-710 Pulse Oximeter is a hand held oximeter, provides patient vital signs such as pulse rate, blood oxygen saturation and perfusion index by placing the sensors to the appropriate site of patient. The device is composed with display, control circuit and panel, and input part for SpO2 sensors. It detects SpO2 and PR using specific sensors. The detected analog signal amplified and converted to digital. This converted data feed to the CPU and converted to the display format as number and waveform. This device is incorporated with alarm system. The alarm generated when the detected signal range is beyond the user set alarm limits. BT-710 Pulse Oximeter features 4.3" color touch screen, Hand held style, Measure SpO2 pulse rate. Accurate SpO2 performance during motion and low perfusion. Specialized PC Software for data review and analysis. Over 8 hours of continuous working on rechargeable lithium-ion battery. 5V DC input with convenient Micro-USB battery. Suitable for adult, paediatric and infant.</p>
DEVICE INTENDED PURPOSE	<p>The Bistos BT-710 Pulse Oximeter is intended to acquire the physiological signals blood oxygen saturation (SpO2) and pulse rate (PR). The signals are converted into digital data and processed, examines the data for alarm conditions and display the data. The device also provides operating control for the user. The devices intend to use in hospital clinical area to provide additional information to the medical and nursing staff about the physiological condition of the patient. The devices are intended to be used only under regular supervision of clinical personnel. It is suitable for adult and pediatric. The intended locations of use are hospitals and clinics.</p>
VALIDITY DATE OF REGISTRATION	06/01/2020 - 05/01/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PULSE OXIMETER	BT-710