




DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	BION MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB3492221-65288
BRAND NAME	BION
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The pulse oximeter is used to measure arterial oxygen saturation (% SpO2), the percentage of oxyhemoglobin (HbO2) relative to the total hemoglobin (Hb). It also measures the pulse rate (PR, the number of pulse beats per minute), and gives the perfusion index, an indication of pulse strength at the monitoring site.
DEVICE INTENDED PURPOSE	The pulse oximeter uses the non-invasive optical transmittance method to measure arterial oxygen saturation and pulse rate. Do not use it for continuous care for patients.
VALIDITY DATE OF REGISTRATION	18/06/2021 - 17/06/2026

LIST OF DEVICE

NO	NAME OF DEVICE 	IDENTIFIER
1	FingerTip Pulse Oximeter	P100
2	FingerTip Pulse Oximeter with Blue tooth	P100BT