

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 DICAL DEVICE AUTHORITY	IDENTIFIER
1	FingerTip Pulse Oximeter	P100
2	FingerTip Pulse Oximeter with Blue tooth	P100BT