



DEVICE DETAILS

NAME OF DEVICE	HANDHELD PULSE OXIMETER
ESTABLISHMENT NAME	CYPRESS MEDIC SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC1940625-204378
BRAND NAME	ROSSMAX
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Rossmax Pulse Oximeter is used to measure arterial oxygen saturation (% SpO2) of hemoglobin and pulse rate, an important indicator of respiratory function. ACT (Artery Check Technology) analyzes the pulse and SpO2 signals and determines the actually prevailing stiffness of the artery (Artery Condition). It further classifies the vascular status into 6 levels. Rossmax probe combined with pulse oximeter is to spot-check oxygen saturation in blood (SpO2) and pulse rate.
DEVICE INTENDED PURPOSE	SA Series: Rossmax Handheld Pulse Oximeter is used to measure oxygen saturation in blood (SpO2) and pulse rate, also to issue warnings immediately. The model of handheld pulse oximeter, only for SA300, has an ACT (Artery Check Technology) analysis function that analyzes the pulse and SpO2 signals and determines the actually prevailing stiffness of the artery (Artery Condition). It is a non-invasive device intended for spot-check of adults, child, and infants with corresponding probe applied at home, hospital and clinics. The probe contains a dual light source and a photodetector. Probe: The probe combined with pulse oximeter is to spot-check oxygen saturation in blood (SpO2) and pulse rate. The different probes combined with pulse oximeter is used on adults, neonatal, pediatric at hospital, clinics, and/or home.
VALIDITY DATE OF REGISTRATION	04/06/2025 - 03/06/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	SA300
2	Pulse Oximeter	SA310
3	Probe	PA100
4	Probe	PB100
5	Probe	PC100
6	Probe	PD100
7	Probe	PF100

