



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	SURIA-MEDIK SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC10153821-73656
BRAND NAME	CHARMCARE
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	The SpO2 function is indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of patients. The device is reusable. Accessories connected to the device will be contacted to the patient's finger. Pulse oximeter is equipped with validated software for operation. Accessories include SpO2 finger probe which is either reusable or disposable.
DEVICE INTENDED PURPOSE	The intended use of CX130 is detecting and measurement as below parameters to provide and help doctors for making figure out the patient's vital condition. • Exact and stable Oxygen saturation of arterial blood • Accurate Pulse Rate Especially, CX130 has AGC (Auto Gain Controller) function for weak pulsatile patients. The device is to detect and control its gain automatically in accordance with patient's pulse rate strength. Designed for hospital, transport and home use.
VALIDITY DATE OF REGISTRATION	14/09/2021 - 13/09/2026



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	CX130
2	Adult Reusable SpO2 Sensor	S01-300
3	AA Alkaline Battery	BT1
4	Adapter with Power Cord	DC2-100
5	Protective Boot Cover	BTC-100
6	Reusable SpO2 Sensor (pediatric)	S02-300
7	Reusable SpO2 Sensor (neonate)	S03-300
8	Reusable SpO2 Sensor (neonate)	S10-300
9	SpO2 Extension Cable	EXT-100
10	IV Pole Clamp	CMP-100

