



DEVICE DETAILS

NAME OF DEVICE	HAND HELD PULSE OXIMETER WITH SPO2 PROBE SENSOR
ESTABLISHMENT NAME	GASWORLD SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC16137237017
BRAND NAME	ACARE
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>AH-MX PULSE OXIMETER IS A HIGH QUALITY AND WELL-FUNCTIONED DEVICE TO CHECK PATIENT'S BLOOD OXYGEN SATURATION (SPO2) LEVEL AND PULSE RATE. AS A PORTABLE, CONVENIENT AND RELIABLE PHYSIOLOGICAL MONITORING DEVICE, HANDHELD PULSE OXIMETER AH-MX CAN GREATLY ENHANCES PATIENT CARE. THE AH-M1 HANDHELD PULSE OXIMETER IS INTENDED FOR CONTINUOUSLY MONITORING OR SPOT CHECKING PERIPHERAL OXYGEN SATURATION (SPO2) AND PULSE RATE (PR) FOR ADULT, PEDIATRIC OR NEONATAL PATIENTS. THIS DEVICE CAN BE USED IN INSTITUTIONS OR UNITS WITH HEALTHCARE CAPABILITY. THIS INCLUDES OUTPATIENT DEPARTMENTS, EMERGENCY ROOMS AND DEPARTMENTS OF INTERNAL MEDICINE IN HOSPITALS, ORDINARY DEPARTMENTS IN CLINICS, NURSING HOSPITALS AND COMMUNITY MEDICAL INSTITUTIONS. IT MAY ALSO BE USED IN THE HOME.</p>
DEVICE INTENDED PURPOSE	<p>THE AH-MX SERIES PULSE OXIMETER IS INTENDED FOR MEASURING AND DISPLAYING FUNCTIONAL OXYGEN SATURATION OF ARTERIAL HEMOGLOBIN (SPO2) AND PULSE RATE FOR ADULT, PEDIATRIC IN FAMILY, HOSPITAL (INCLUDING CLINICAL USE IN INTERNIST/SURGERY, ANESTHESIA, INTENSIVE CARE AND ETC.), OXYGEN BAR, SOCIAL MEDICAL ORGANIZATIONS, PHYSICAL CARE IN SPORTS(IT CAN BE USED BEFORE OR AFTER SPORTS. CONTINUOUSLY MONITORING IS NOT RECOMMENDED.)</p>
VALIDITY DATE OF REGISTRATION	02/06/2017 - 01/06/2022

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Handheld Pulse Oximeter	AH-MX
2	SPO2 Probe Sensor	ASANR-D1
3	SPO2 Probe Sensor	ASSNR-D1

NO	NAME OF DEVICE	IDENTIFIER
4	SPO2 Probe Sensor	ASPNR-D1
5	SPO2 Probe Sensor	ASYNR-D1
6	SPO2 Probe Sensor	ASDNR-N3
7	SPO2 Probe Sensor	ASANR-D1
8	SPO2 Probe Sensor	ASSNR-D1
9	SPO2 Probe Sensor	ASPNR-D1
10	SPO2 Probe Sensor	ASYNR-D1



MEDICAL DEVICE AUTHORITY