



DEVICE DETAILS

NAME OF DEVICE	AVOXIMETER
ESTABLISHMENT NAME	STRAITS SCIENTIFIC (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	IVDC6964423-138694
BRAND NAME	ACCRIVA DIAGNOSTICS
MEDICAL DEVICE CATEGORY	POINT OF CARE TESTING
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	THE AVOXIMETERS ARE BLOOD GAS SYSTEM THAT MEASURE WHOLE BLOOD BLOOD GAS USING DISPOSABLE SINGLE-USE CUVETTES.AVOXIMETER SYSTEMS HAVE TWO MODELS WHICH ARE AVOXIMETER 1000E AND AVOXIMETER 4000. THEY ARE VARIANT ONLY IN THE THROUGHPUT AND THE READING WAVELENGTH FOR THESE 2 MODELS OF AVOXIMETERS.
DEVICE INTENDED PURPOSE	THE AVOXIMETER 1000E IS A BATTERY-OPERATED BEDSIDE WHOLE BLOOD OXIMETER THAT PERFORMS INDIVIDUAL POINT-OF-CARE MEASUREMENTS OF OXYHEMOGLOBIN SATURATION (%HB02) AND TOTAL HEMOGLOBIN CONCENTRATION [THB] ON LITHIUM/SODIUM OR HEPARIN OR EDTA ANTICOAGULATED WHOLE BLOOD SAMPLES. OXYGEN CONTENT [O2] OF THE BLOOD SAMPLE IS AUTOMATICALLY CALCULATED FROM THE %HB02 AND THB MEASUREMENTS. THE AVOXIMETER 4000 IS A BATTERY-OPERATED DESKTOP WHOLE BLOOD OXIMETER THAT PERFORMS INDIVIDUAL POINT-OF-CARE MEASUREMENTS OF TOTAL HEMOGLOBIN (THB), OXYHEMOGLOBIN SATURATION (%02HB), CARBOXYHEMOGLOBIN (%COHB), AND METHEMOGLOBIN (%METHB) ON FRESHLY-DRAWN OR HEPARIN- OR EDTA-ANTICOAGULATED WHOLE BLOOD SAMPLES. OXYGEN CONTENT ([O2CT]), PERCENT SATURATION (SO2) AND OXYGEN CARRYING CAPACITY (O2CAP) OF THE BLOOD SAMPLE ARE AUTOMATICALLY CALCULATED FROM THE %HB02 AND THB MEASUREMENTS
VALIDITY DATE OF REGISTRATION	06/07/2023 - 05/07/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	AVOXimeter 4000 System	AVOX4000-INT
2	AVOXimeter 1000E System	AVOX1000E-INT
3	AVOXimeter 4000 Cuvettes	QV8
4	Quality Control Filters	4-QCYO

NO	NAME OF DEVICE	IDENTIFIER
5	Optical Quality Control Filters	E-QCYO
6	AVOXimeter 1000E Cuvettes	C100B
7	Temperature Probe	4-TMPB

