



## DEVICE DETAILS

NAME OF DEVICE	AVOXIMETER
ESTABLISHMENT NAME	STRAITS SCIENTIFIC (M) SDN BHD
REGISTRATION NO	IVDC6964423-138694
BRAND NAME	ACCRIVA DIAGNOSTICS
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 [02] 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 ([02CT]), 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
No results found.		