



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	AVOXIMETER
<b>ESTABLISHMENT NAME</b>	STRAITS SCIENTIFIC (M) SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	IVDC6964423-138694
<b>BRAND NAME</b>	ACCRIVA DIAGNOSTICS
<b>MEDICAL DEVICE CATEGORY</b>	POINT OF CARE TESTING
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	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.
<b>DEVICE INTENDED PURPOSE</b>	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 (%O2HB), 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
<b>VALIDITY DATE OF REGISTRATION</b>	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

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

