

Nova 4/12 TCO2 Sensor Lot Number 25023033

Ref Number 14715 Exp Date 2027-01-23 Date of Manufacture 2025-01-23 UDI# (01)00385480147156(11)250123(17)270123(10)25023033

	Spec*	Pass/Fail
Slope	9.5 - 14.3	Pass
Chem Control L2	28 - 34	Pass
Chem Control L3	12 - 16	Pass
Std. A mV	- 140 to +140	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications.

<sup>1</sup>Note: The process for assigning values to Nova Biomedical Quality Control and Linearity Solutions utilizes multiple sources of test data inputs to establish the ranges for each analyte in each lot, which may result in small lot-to-lot variation in insert range values.

<sup>2</sup>Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector Title

<u>1/31/2025</u> Date