

CERTIFICATE OF ANALYSIS

PCO2 Internal Filling Solution Lot Number 23313078 Ref Number 06553 Exp Date 2024-11-09 Date of Manufacture 2023-11-09 UDI# (01)00385480065535(11)231109(17)241109(10)23313078

<u>Spec</u> <u>Pass/Fail</u> NaCl mmol/L 145.5 - 154.5 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. All listed analytes are traceable to NIST SRM Materials.

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.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer.

Amishi.M

Approval

QC Inspector

Title

11/28/2023

Date