



CERTIFICATE OF COMPLIANCE

This product has been manufactured in compliance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) standards and meets Nova Biomedical product specifications.

| | | | |
|---------------------------------|--|------------------|---------------|
| Customer: | NIA | | |
| Description: | TEST STRIPS, STATSTRIP™ KETONE, PACKAGED 50 CT | | |
| Catalog Number: | 46951 | | |
| Nova Biomedical P/N | 46951 | | |
| <u>Target Range</u> | <u>MPE</u> | <u>SD/CV (%)</u> | |
| 0.1-0.8 mmol/L | +/- 0.3 mmol/L | ≤ 0.3 mmol/L | (PASS) / FAIL |
| 1.5-2.5 mmol/L | +/- 20% | ≤ 15% | (PASS) / FAIL |
| 3.5-5.0 mmol/L | +/- 20% | ≤ 15% | (PASS) / FAIL |
| Qty: | 13,626 | | |
| Lot No. | 2224134249 | | |
| Mfg. Date: | 2024-05-13 | | |
| Expiration Date: | 2024-05-13 | | |
| Unique Device Identifier (UDI): | (01)20385480 469511 (11) 240513 (17) 260513 (10) 2224134249 | | |

Quality Control Manager

Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454