nova biomedical

# 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.

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|---|---|
| Customer: | LIFESCAN |
| Description: | TEST STRIPS, STATSTRIP ™ GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT |
| Lifescan Purchase Order No.: | 475634 |
| Catalog Number: | 42214 |
| Nova Biomedical P/N | 54311 |
| One Touch P/N | 02307501 |
| Target Range (mg/dL) / SD(mg/dL) /CV (%) | |
| 30-50 / ≤ 4 mg/dL | (PASS) / FAIL |
| 51-110 / ≤ 6.0% | (PASS) / FAIL |
| 111-150 / ≤ 5.0% | (PASS) / FAIL |
| 151-250 / ≤ 5.0% | (PASS) / FAIL |
| 251-400 / ≤ 5.0% | (PASS) / FAIL |
| Accuracy Criteria 1: Total within +/-12 mg/dL or +/-12% of reference method ≥ 95% | (PASS) / FAIL |
| Accuracy Criteria 2: Total within +/-15 mg/dL or +/-15% of reference method ≥ 98% | (PASS) / FAIL |
| Qty: | 12,096 |
| Lot No. | 0324086309 |
| Date of Mfg. (DOM): | 2024 / 03 / 26 (YYYY/MM/DD) |
| Expiration Date: | 2026 / 09 (YYYY/MM) |
| Unique Device Identifier (UDI): | (01)20385480422141<br>(11)240326<br>(17)260926<br>(10)0324086309 |

Marc Brodeur 4/23/2024

Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454



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