



**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:   | LIFESCAN   |             |
| Description:  | TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT  |             |
| Lifescan Purchase Order No.:  | 639998   |             |
| Catalog Number:   | 42214  |             |
| Nova Biomedical P/N   | 54515  |             |
| One Touch P/N   | 02315302   |             |
| 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:  | 9,072  |             |
| Lot No.   | 0324113249   |             |
| Date of Mfg. (DOM):   | 2024 / 04 / 22 (YYYY/MM/DD)                                      |             |
| Expiration Date:  | 2026 / 04 / 22 (YYYY/MM/DD)                                      |             |
| Unique Device Identifier (UDI):   | (01)20385480422141<br>(11)240422<br>(17)260422<br>(10)0324113249 |             |

Mark Broome 5/2/24  
 Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454

