



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.: | 460442 | | |
| Catalog Number: | 42214 | | |
| Nova Biomedical P/N | 54311 | | |
| One Touch P/N | 02307501 | | |
| Target Range (mg/dL) | Mean MPE (%) | CV (%) | |
| 60-75 | ≤ 15 | ≤ 6.5 | PASS / FAIL |
| 120-160 | ≤ 15 | ≤ 5.5 | PASS / FAIL |
| 250-290 | ≤ 15 | ≤ 5.0 | PASS / FAIL |
| 380-420 | ≤ 15 | ≤ 5.0 | PASS / FAIL |
| 500-540 | ≤ 15 | ≤ 5.0 | PASS / FAIL |
| Combined MPE (%) | ≤ 10 | | PASS / FAIL |
| Qty: | 6,048 | | |
| Lot No. | 0323219309 | | |
| Date of Mfg. (DOM): | 2023 / 08 / 07 (YYYY/MM/DD) | | |
| Expiration Date: | 2026 / 02 (YYYY/MM) | | |
| Unique Device Identifier (UDI): | (01)20385480422141 (11)230807 (17)260207 (10)0323219309 | | |

Mariborne
 Quality Control Manager

8/17/2023
 Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454