



**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:           | NIPRO DIAGNOSTICS INC.                                     |                  |  |
| Description:        | TEST STRIPS, NIPRO STATSTRIP™<br>KETONE, PACKAGED 20<br>CT |                  |  |
| Catalog Number:     | 54288  |                  |  |
| Nova Biomedical P/N | 54288  |                  |  |
| <u>Target Range</u> | <u>MPE</u>   | <u>SD/CV (%)</u> |  |
| 0.1-0.8 mmol/L      | +/- 0.3 mmol/L   | ≤ 0.1 mmol/L     | <input checked="" type="radio"/> PASS / <input type="radio"/> FAIL |
| 1.5-2.5 mmol/L      | +/- 20%  | ≤ 10%            | <input checked="" type="radio"/> PASS / <input type="radio"/> FAIL |
| 3.5-5.0 mmol/L      | +/- 20%  | ≤ 10%            | <input checked="" type="radio"/> PASS / <input type="radio"/> FAIL |
| Qty:                | 954  |                  |  |
| Lot No.             | 2225121249   |                  |  |
| Mfg. Date:          | 2025-05-01   |                  |  |
| Expiration Date:    | 2027-05-01   |                  |  |

  
Quality Control Manager

5/13/25  
Date

Nova Biomedical Corporation      200 Prospect Street      Waltham, MA 02454