



**CERTIFICATE OF COMPLIANCE Page 1/2**

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.

The enzyme levels meet the following specifications:

- iii) Test Inspection Item: Glucose + Enzymes (oxidized form)  $\geq$  1.0 IU per strip
- iv) Test Inspection Item: Ferrocyanide  $\geq$  20  $\mu$ g per strip

Customer:	NIPRO - ODATE FACTORY	
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE, 25 COUNT, COLUMN (RAW MATERIAL)	
Catalog Number:	59363	
Nova Biomedical P/N	59363	
Target Range (mg/dL)	SD(mg/dL) /CV (%)	
30-50	$\leq$ 4 mg/dL	<u>PASS</u> / FAIL
51-110	$\leq$ 6.0%	<u>PASS</u> / FAIL
111-150	$\leq$ 5.0%	<u>PASS</u> / FAIL
151-250	$\leq$ 5.0%	<u>PASS</u> / FAIL
251-400	$\leq$ 5.0%	<u>PASS</u> / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method $\geq$ 95%		<u>PASS</u> / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method $\geq$ 98%		<u>PASS</u> / FAIL
Qty:	23,175	
Lot No.	2125084309	
Mfg. Date:	2025-03-25	
Expiration Date:	2027-09-25	

Mark Broome                      4/2/25  
 Quality Control Manager                      Date

Nova Biomedical Corporation                      200 Prospect Street                      Waltham, MA 02454



