



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:	N/A
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 1800 COUNT
Catalog Number:	42214
Nova Biomedical P/N	51493
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:	7,350
Lot No.	0324260309
Mfg. Date:	2024-09-16
Expiration Date:	2027-03-16
Unique Device Identifier (UDI):	(01)20385480422141 (11) <u>240916</u> (17) <u>270316</u> (10) <u>0324260309</u>

Mark Broome
 Quality Control Manager

10/2/24
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454