



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™ KETONE, PACKAGED 50 CT		
Catalog Number:	46951		
Nova Biomedical P/N	46951		
<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	PASS / FAIL
1.5-2.5 mmol/L	+/- 20%	≤ 10%	PASS / FAIL
3.5-5.0 mmol/L	+/- 20%	≤ 10%	PASS / FAIL
Qty:	26,460		
Lot No.	2226012249		
Mfg. Date:	2026-01-12		
Expiration Date:	2028-01-12		
Unique Device Identifier (UDI):	(01)20385480 469511 (11) 260112 (17) 280112 (10) 2226012249		


 Quality Control Manager

1/29/26
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454