



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™ KETONE, PACKAGED 20 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
	1.5-2.5 mmol/L	+ - 20%	≤ 10%
	3.5-5.0 mmol/L	+ - 20%	≤ 10%
	PASS / FAIL PASS / FAIL PASS / FAIL		
Qty:	846		
Lot No.	2225323249		
Mfg. Date:	2025 - 11 - 19		
Expiration Date:	2027-11-19		


 Quality Control Manager

12/9/25
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454