



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:	NIA
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 ≤ 0.3 mmol/L	PASS / FAIL
1.5-2.5 mmol/L +- 20% ≤ 15%	PASS / FAIL
3.5-5.0 mmol/L +- 20% ≤ 15%	PASS / FAIL
Qty:	4,410
Lot No.	2224141249
Mfg. Date:	2024-05-20
Expiration Date:	2026-05-20
Unique Device Identifier (UDI):	(01)20385480 469511 (11) 240520 (17) 260520 (10) 2224141249

Marc Proome
Quality Control Manager

5/31/2024
Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454