nova biomedical

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
Target Range / MPE / SD/CV (%) 0.1-0.8 mmol/L +- 0.3 mmol/L ≤ 0.3 mmol/L 1.5-2.5 mmol/L +- 20% ≤ 15% 3.5-5.0 mmol/L +- 20% ≤ 15%	PASS / FAIL PASS / FAIL PASS / FAIL
Qty:	1,001
Lot No.	2224191249
Mfg. Date:	2024.07.09
Expiration Date:	2026.07.31

Marc Browne 7/29/24

Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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