nova biomedical

CERTIFICATE OF COMPLIANCE Page 1/2

This product has been manufactured in compliance with ISO 13485:2012 and Medical Device Single Audit Program (MDSAP) standards and meets Nova Biomedical product specifications.

Customer:	NIPRO DIAGNOSTICS INC.
Description:	TEST STRIPS, NIPRO STATSTRIP ™ GLUCOSE, PACKAGED
Catalog Number:	48880
Nova Biomedical P/N	48880
Target Range (mg/dL) Mean MPE (%) CV (%)	
60-75 ≤ 15 ≤ 6.5	PASS / FAIL
120-160 ≤ 15 ≤ 5.5	PASS / FAIL
250-290 ≤ 15 ≤ 5.0	PASS / FAIL
380-420 ≤ 15 ≤ 5.0	PASS / FAIL
500-540 ≤ 15 ≤ 5.0	PASS / FAIL
Combined MPE (%) ≤ 10%	PASS / FAIL
Qty:	106
Lot No.	2121327309
Mfg. Date:	2021.11.23
Expiration Date:	2024.05.31

Marc Broome 11/30/2021

Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

Released Confidential

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ADDENDUM TO CERTIFICATE OF COMPLIANCE Page 2/2

RELEASE TEST RESULTS

Customer:	NIPRO DIAGNOSTICS INC.
Description:	TEST STRIPS, NIPRO STATSTRIP ™ GLUCOSE