



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:	LIFESCAN	
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT	
Lifescan Purchase Order No.:	497596	
Catalog Number:	42214	
Nova Biomedical P/N	54311	
One Touch P/N	02307501	
Target Range (mg/dL)	SD(mg/dL) /CV (%)	
30-50	≤ 4 mg/dL	<u>PASS</u> / FAIL
51-110	≤ 6.0%	<u>PASS</u> / FAIL
111-150	≤ 5.0%	<u>PASS</u> / FAIL
151-250	≤ 5.0%	<u>PASS</u> / FAIL
251-400	≤ 5.0%	<u>PASS</u> / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/-12% of reference method ≥ 95%		<u>PASS</u> / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/-15% of reference method ≥ 98%		<u>PASS</u> / FAIL
Qty:	30,240	
Lot No.	0325171309	
Date of Mfg. (DOM):	2025/06/20 (YYYY/MM/DD)	
Expiration Date:	2027/12 (YYYY/MM)	
Unique Device Identifier (UDI):	(01)20385480422141 (11)250620 (17)271220 (10)0325171309	

Maie Bowne
 Quality Control Manager

7/14/25
 Date

