



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.:	500854	
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	PASS / FAIL
51-110	≤ 6.0%	PASS / FAIL
111-150	≤ 5.0%	PASS / FAIL
151-250	≤ 5.0%	PASS / FAIL
251-400	≤ 5.0%	PASS / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%		PASS / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%		PASS / FAIL
Qty:	30240	
Lot No.	0325248309	
Date of Mfg. (DOM):	2025 / 09 / 05 (YYYY/MM/DD)	
Expiration Date:	2028 / 03 (YYYY/MM)	
Unique Device Identifier (UDI):	(01)20385480422141 (11) 250905 (17) 280305 (10) 0325248309	

Maureen Broome 9/19/25
 Quality Control Manager Date

