



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.:	450481		
Catalog Number:	42214		
Nova Biomedical P/N	54311		
One Touch P/N	02307501		
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:	6,048		
Lot No.	0323103309		
Date of Mfg. (DOM):	2023 / 04 / 13 (YYYY/MM/DD)		
Expiration Date:	2025 / 10 (YYYY/MM)		
Unique Device Identifier (UDI):	(01)20385480422141 (11)2 3 0 4 1 3 (17)2 5 1 0 1 3 (10)0 3 2 3 1 0 3 3 0 9		

Marc Broome 4/19/2023
 Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454