

OI-922 Page 40 of 66 Rev. BH Viald and Packaged Test Strip Release Test Strips



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.:	445927
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:	36,288
Lot No.	0323044309
Date of Mfg. (DOM):	2023/02/13 (YYYY/MM/DD)
Expiration Date:	2025/08 (YYYY/MM)
Unique Device Identifier (UDI):	(01)20385480422141 (11)230213 (17)250813 (10)0323044309

Mar Broome
Quality Control Manager

2/22/23
Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454