SD BIOSENSOR, INC.
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Certificate of Analysis

Product Name				
Cat. No.				
LOT No.		MFG Date		
		EXP Date		
Test Strip EXP Date		C.S. EXP Date		
Quantity		Date of Release		

Testing categories		Specification	Result
METER	Appearance Inspection	No scratch, stain and crack etc.	*Pass*
		Printing of case and LCD window	*Pass*
	Mechanical Part	Uniform Gap between top and bottom case	*Pass*
		Button operation: ON/OFF, left & right button	*Pass*
		Button assembly condition	*Pass*
		Test strip can be inserted into the strip slot.	*Pass*
	Electronic Part	Quiescent supply current: Where power off: ≤20uA / Where measuring: ≤1.8mA	*Pass*
		Performance: check strip(30uA) Criteria 30±0.15uA / environmental temperature ±3℃	*Pass*
		Auto-start: For inserting a test strip, no auto-starting	*Pass*
STRIP 01GC10/ 01GC11	Appearance Inspection	Test strip size: W: 5.5±0.05mm / L: 30±0.05mm	*Pass*
		Quantity per one container: 10 T/vial	*Pass*
	Repeatability	Low: CV ≤ 5%, Mid/High: CV ≤ 4%	*Pass*
	Coding test	Testing temperature range: 10-40℃	50-104℉ / Testing Range: 10-600mg/dL	0.6-33.3mmol/L	*Pass*
C.S. 01GC11	Accuracy	Reference Criteria: Level-M 76-84mg/dL	4.2-4.7mmol/L	*Pass*
	Repeatability	CV ≤ 4%	*Pass*
PACKING	Packaging Inspection	Packing list: **[01GC10]** Meter / Test strip (10T) / Check strip / Battery / Code chip / 10 Lancets / Lancing device / Carrying case / User guide / Quick guide / Self test diary / Test strip package insert **[01GC11]** Meter / Test strip (10T) / Check strip / Battery / Code chip / C.S.(Level M) / 10 Lancets / Lancing device / Carrying case / User guide / Quick guide / Self test diary / Test strip package insert/C.S. package insert **[01GC12]** Meter / Check strip / Battery / 10 Lancets / Lancing device / Carrying case / User guide / Quick guide **[01GC13]** Meter / Check strip / Battery / Lancing device / Carrying case / User guide / Quick guide	*Pass*
		[01GC10/01GC11] Expiration date between test strip label and package	*Pass*
		[01GC10/01GC11] Code chip number between vial label and code chip	*Pass*
		[01GC10/01GC11] LOT No. between test strip label and package	*Pass*
	Check Strip Test	To display OK message	*Pass*

*C.S.: Glucose Control Solution

According to SD Biosensor quality assurance system, the above QC tests have been completed and passed the specification. We hereby approve this product release.

* Date issued :

SunYoung Jeong
Manager of Regulatory Affairs & QA Dept.
SD Biosensor, Inc.