



# **Veri-Q Balance Glucose Monitoring System**

Nov, 2015

Specialized and Professional for POCT (Point of Care Testing)

<http://www.micobiomed.com>

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## 1. Specification of Meter

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**G3 : MGD-1002**



- **Weight** 25g (without batteries)
- **Power** 1.5V Lithium Battery ×2
- **Size** 6 × 7 × 2 (cm)
  
- **Measuring Range** 20~600mg/dL
- **Operation temperature** 10 ~ 40°C
- **Number of Measurement** 1,000 tests
- **Memory** 500 tests
- **Blood Sample** 0.5μl, Capillary
- **Measuring Time** 5 Sec

# 1. Specification of Strip



Certificato KR11/01749

The management system of

**MiCoBioMed Co.,Ltd.**  
R-2F, 55-13 Shingeeonj-dong, Anseong-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

**ISO 13485:2003**  
**EN ISO 13485:2012**

For the following activities

**Design, Development and Manufacture of Blood glucose monitoring system for self-test, consisting of blood glucose test strip, blood glucose meter, control solution and Multi Function Glucose/Cholesterol/Hemoglobin Blood Monitoring System for self test**

This certificate is valid from 19 November 2012 until 28 December 2014 and remains valid subject to satisfactory surveillance audits. The certification audit due before 13 December 2014 Issue 3. Certified since 28 December 2011

Authorized by

SGS Limited (Kingdom of the Netherlands) Systems & Services Certification  
Rosedown Business Park, Elsternham Park, Cheshire, CH65 3EN, UK  
t +44 (0)151 300-6066 f +44 (0)151 300-6000 www.sgs.com

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문서화인번호: 1330-4992-9310-0119 (신청인 : 나관구)

**KFDA**

제약 12-260 호

**의료기기 제조 허가증**

업허가번호 : 제 3162호

구분	제조	상목/분류	상목
제품명 (상품명, 품목명, 모델명)	Veri-Q, 개인용혈당측정기, MGD-1001	분류번호 (등급)	A22030.02(3)
모양 및 구조	발행		
원재료	발행		
제조방법	발행		
사용목적	사용목적 : 발행, 성능 : 발행		
사용법	발행		
사용 시 주의사항	발행		
포장단위	발행		
지정방법 및 사용기간	지정방법 : 발행, 사용(사용기간) : 발행		
시험규격	발행		
제조(수입)일자 정보	제조(수입)일자 : (주)미코바이오메드, 경기도 안성시 궁단리로 116 (주)코미 (주)키엠 2층 (신안지점)		
허가조건	제조원 : 발행		
비고	임의용의용기기, 한발구성의용기기(개인용혈당측정기 A22030.02 [3], 임의용수동형식 A53070.02 [2], 의료기구형발행 A38090.05 [1]), 혈당측정장치 H10010.01 [1])		

「의료기기법」 제6조 및 같은 법 시행규칙 제5조제2항에 따라 위와 같이 허가합니다.

2012년 02월 28일

**식품의약품안전청장**

본 증명서는 인터넷으로 발급되었으며, 민원24(www.mw.go.kr)의 민원발급금영서민확인 메뉴를 통해 위·변조 여부를 확인할 수 있습니다. (발급일로부터 90일(90일) 동안 발급처(발급처) 또는 신청처(신청처)에 문의하십시오.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
1515 E. Kettella Ave. Unit 2115  
ANAHEIM CA 92805

June 19, 2013

Re: K123007  
Trade/Device Name: Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: I  
Product Code: NFW, CGA, JJK  
Dated: May 28, 2013  
Received: May 30, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

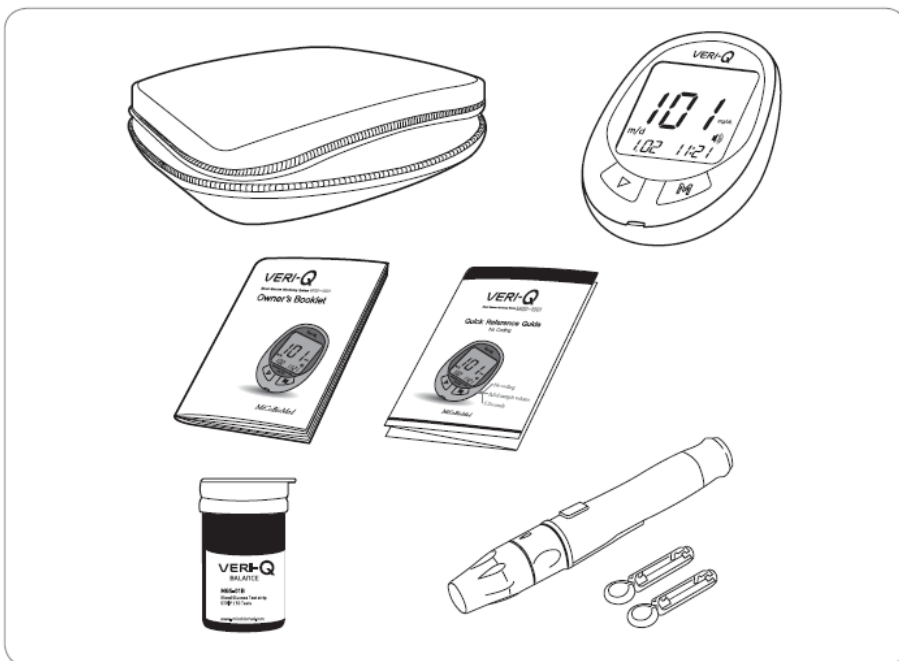
Food and Drug Administration  
1515 E. Kettella Ave. Unit 2115  
ANAHEIM CA 92805

June 18, 2012

Re: K123016  
Trade/Device Name: Veri-Q self testing MGD-2001 Blood Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: II  
Product Code: NFW, CGA, JJK  
Dated: May 09, 2013  
Received: May 09 2013

## 2. Package Contents

### DEVICE



### STRIP



Test Strip Vial

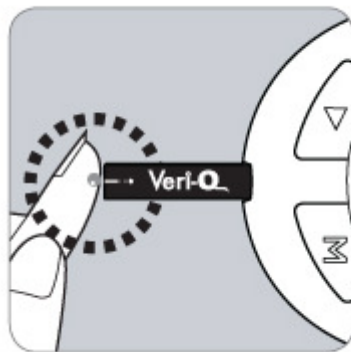
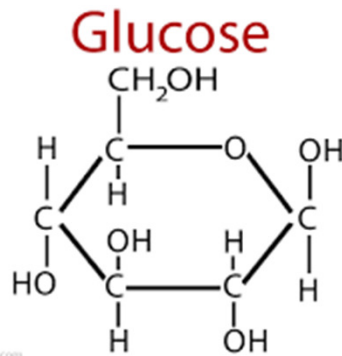


MGS-01A Test Strip

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## 3. Target Market

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Commercial Market

Drug Store

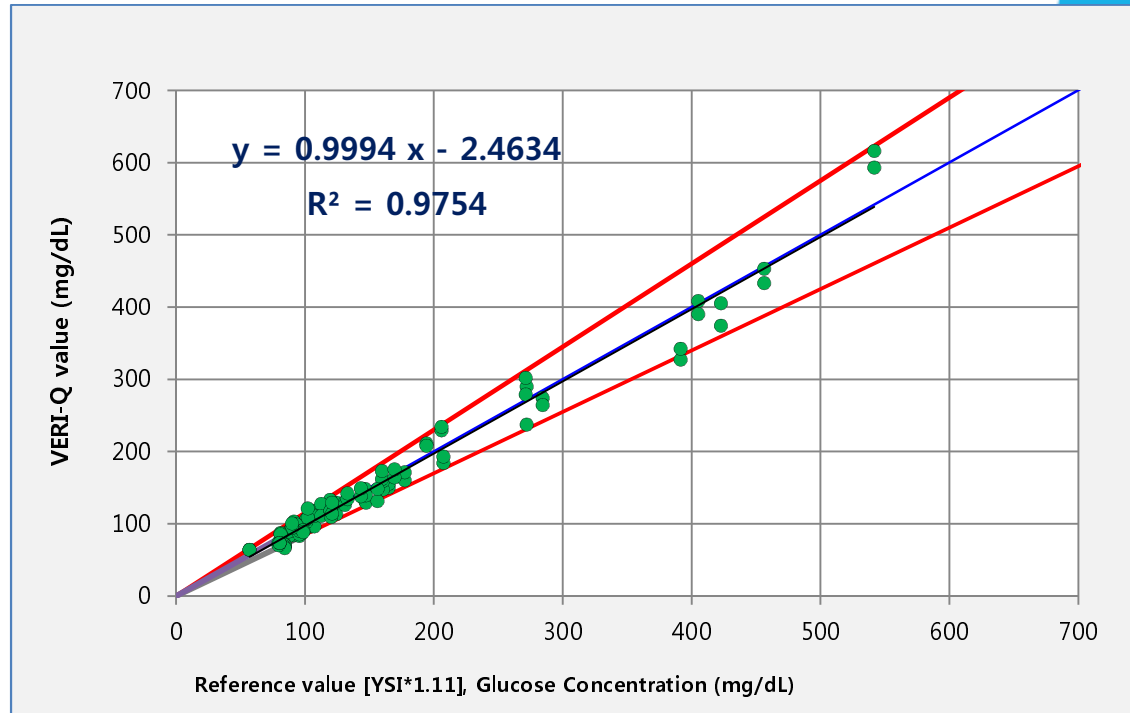
National HealthCare

Doctor's Office

Government

**Target Profile**

## 4. Linearity analysis



	within ±5%	within ±10%	within ±15%
Glucose conc. < 100mg/dL	14/38 (36.8%)	28/38 (73.7%)	36/38 (94.7%)
Glucose conc. ≥ 100 mg/dL	32/72 (44.4%)	56/72 (77.8%)	69/72 (95.8%)

# Blood Glucose Monitoring System

# VERI-Q BALANCE

**Code - Free**

Blood Glucose Monitoring System



- Code-free
- 0.5  $\mu$ L blood sample
- Test result within 5 sec.
- 20~600 mg/dL (1.1~33.3 mmol/L)
- Auto turn-off
- Test averaging
- After meal test result mark
- Special test result mark



Test Averaging



0.5 $\mu$ L



Code-Free



5 sec.



Special Marks



Data Management





**Thank You**