

Declaration of Conformity

Manufacturer

Name: All Medicus Co., Ltd.

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European Representative

Medical Technology Promedt Consulting GmbH, Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany

Product

Blood Glucose Monitoring System

Model

- AGM-513S (GlucoDr.S™)
- Blood Glucose Test Meter
 - Blood Glucose Test Strip
 - Control Solution

[Others]

- Lancing Device
- Lancets

* Please refer to ATTACHMENT 1. Lancets DoC, ATTACHMENT 2. Lancing Device DoC

Components

1. Blood Glucose Test Meter
 - Meter (1ea)
 - Lancing Device (1ea)
 - Lancet (10ea)
2. Blood Glucose Test Strip
 - Blood Glucose Test Strip (25Tests x 2ea)
3. Control Solution
 - Control Solution 1
 - Control Solution 2

No.	Product No	Product Name	REF Number
1	AM01	AGM-513S, GlucoDr.S Blood Glucose Test Meter (mg/dL)	AGM-513S M1
2	AM02	AGM-513S, GlucoDr.S Blood Glucose Test Meter (mmol/L)	AGM-513S M2
3	AM03	AGM-513S, GlucoDr.S Blood Glucose Test Strips (25Tests x 2ea)	AGM-513S S1
4	AM04	Lancing Device	Lancing Device
5	AM05	Lancets (10ea)	Lancets

Classification: List B According to EC Directive 98/79 EC Annex II the following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar

Conformity assessment Route:

- EC Directive 98/79/EC Annex IV without Sections 4 and 6, Full Quality Assurance System
- RoHS Directive 2011/65/EU

We herewith declare and sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices and Directive 2011/65/EU for the restriction of the use of certain hazardous substances in electrical and electronic equipment. All supporting documentation is retained under the premises of the manufacturer. And manufacturer is exclusively responsible for the declaration of conformity.

Standards Applied :

EN ISO 13485:2016, EN ISO 15197:2015, EN 61010-1:2010, EN 61010-2-101:2002, IEC 61010-2-101:2015, EN 13532:2002, EN 13612:2002, EN 13641:2002, EN 13975:2003, EN 14136:2004, EN 18153:2003, EN ISO 14971:2019, ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, EN ISO 17511:2003, EN 61326-1:2013, EN 61326-2-6:2006, EN 61326-2-6:2013, EN ISO18113-1:2011, EN ISO18113-2:2011, EN ISO18113-3: 2011, EN ISO18113-4:2011, EN ISO18113-5:2011, EN ISO15193:2009, EN ISO15194:2009, EN ISO 23640:2015, EN 62366:2008, EN ISO 15223-1:2016, EN 62304:2006, EN 55011:2009/A1:2010, EN IEC 63000:2018

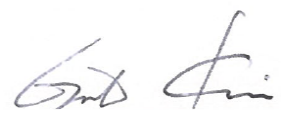
Notified Body

TÜV SÜD Product Service GmbH, Ridlerstraße 65 D-80339 MÜNchen, Germany, CE-0123

(EC) Certificate(s): V1 051016 0042 Rev. 02

Start of CE-marking: March 14, 2016

Place, Date of Issue: Anyang-si, Gyeonggi-do, November 01, 2022

Signature: 
Kim, Gwan Sik, President