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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-245.10.07



Product Service

# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 056720 0014 Rev. 00**

**Manufacturer:**

**AgaMatrix, Inc.**

7C Raymond Avenue  
Salem NH 03079  
USA

**Product Category(ies): Blood glucose measuring systems for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1\\_056720\\_0014\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:V1_056720_0014_Rev.00)

**Report no.:** 72150360

**Valid from:** 2020-08-19

**Valid until:** 2024-05-26

**Date,** 2020-08-19

Christoph Dicks  
Head of Certification/Notified Body



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**No. V1 056720 0014 Rev. 00**

**Model(s):** **Blood Glucose Monitoring System**  
**Blood Glucose Meter**  
**Blood Glucose Test Strips**  
**Control Solution**

**Facility(ies):** AgaMatrix, Inc.  
7C Raymond Avenue, Salem NH 03079, USA

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