



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 15 12 56720 009

**Manufacturer:** **AgaMatrix, Inc.**  
7C Raymond Avenue  
Salem NH 03079  
USA



**EC-Representative:** **MDSS GmbH**  
Schiffgraben 41  
30175 Hannover  
GERMANY

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

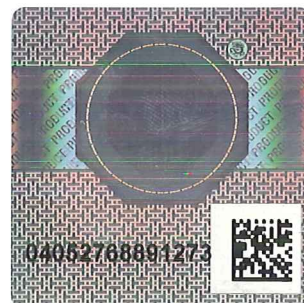
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms 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. See also notes overleaf.

**Report No.:** 72101188

**Valid from:** 2016-04-26  
**Valid until:** 2021-04-25

**Date,** 2016-04-21

  
Stefan Preis



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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No. V1 15 12 56720 009

**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

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