

Product: Blood Glucose Monitoring System sold as:
(See 7010-01296 for part numbers) WaveSense Jazz Blood Glucose Monitoring System

Blood Glucose Meter sold as:
WaveSense Jazz Blood Glucose Meter

Blood Glucose Test Strips sold as:
WaveSense Jazz Test Strips
WaveSense Jazz Duo Test Strips

Glucose Controls sold as:
WaveSense Control Solution
AgaMatrix Glucose Controls

Manufacturer: AgaMatrix, Inc.
7C Raymond Avenue
Salem, NH 03079 USA
603.328.6000
www.agamatrix.com

Product Category: Blood Glucose System, Self-Testing



Medical Device Safety Service (MDSS) GmbH
Schiffgraben 41
30175 Hannover
GERMANY

Device Classification: List B according to Annex II of Directive 98/79/EC

Conformity Assessment Route: Annex IV section 3 of the Directive 98/79/EC
Product Conforms to EN ISO 15197:2015

Notified Body: TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstrasse, 65
80339 München, Germany
No. 0123

Certificate Number: V1 15 12 56720 009

CE marking Start Date: November 13, 2009

AgaMatrix, Inc. declares that the product(s) listed meet the provisions of the Council Directive 98/79/EC for List B on In Vitro Diagnostic Medical Devices and the manufacturer is exclusively responsible for the declaration of conformity.

Place and Date: Salem, NH, USA

May 31, 2017

Signature:



David Olsen
VP Quality Assurance, Regulatory and Clinical Affairs



WaveSense Jazz Wireless Blood Glucose Monitoring System Declaration of Conformity

7410-10226 Rev: C

Product: Blood Glucose Monitoring System sold as:
AgaMatrix WaveSense Jazz Wireless Blood Glucose Monitoring System

Blood Glucose Meter sold as:
AgaMatrix WaveSense Jazz Wireless Blood Glucose Meter

Blood Glucose Test Strips sold as:
AgaMatrix Jazz Test Strips
WaveSense Jazz Duo Test Strips

Glucose Controls sold as:
AgaMatrix Control Solution

Manufacturer: AgaMatrix, Inc.
7C Raymond Avenue
Salem, NH 03079 USA
603.328.6000
www.agamatrix.com

Product Category: Blood Glucose System, Self-Testing
Medical Software



Medical Device Safety Service (MDSS) GmbH
Schiffgraben 41
30175 Hannover
GERMANY

Device Classification: IVD List B according to Annex II of Directive 98/79/EC

Conformity Assessment Route: IVD Annex IV section 3 of the Directive 98/79/EC
Product Conforms to EN ISO 15197:2015

Notified Body: TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstrasse, 65
80339 München, Germany
No. 0123

Certificate Number: V1 15 12 56720 009

CE marking Start Date: September 3, 2015

AgaMatrix, Inc. declares that the product(s) listed meet the provisions of the Council Directive 98/79/EC for List B In Vitro Diagnostic Medical Devices and the manufacturer is exclusively responsible for the declaration of conformity.

Place and Date: Salem, NH May 31, 2017

Signature:

David M. Olsen
VP Quality Assurance, Regulatory and Clinical Affairs