



Declaration of Conformity

Afinion™ HbA1c

Manufacturer name: Abbott Diagnostics Technologies AS

Manufacturer address: Kjelsåsveien 161,
P.O.Box 6863 Rodeløkka
NO-0504 Oslo, Norway

SRN No.: NO-MF-000001423

| Product information: | Product name | Product Code | UDI Code | Basic UDI Code |
|----------------------|---|-----------------------|----------------|------------------|
| | Afinion HbA1c | 1116795 | 07070060013930 | 7070060HBA000136 |
| | Afinion HbA1c | 1116797 | 07070060013978 | 7070060HBA000136 |
| | Afinion HbA1c | 1117196 | 07070060015354 | 7070060HBA000136 |
| | Afinion HbA1c Control | 1116793 | 07070060013909 | 7070060HBA000238 |
| | Afinion HbA1c Control | 1117193 | 07070060015347 | 7070060HBA000238 |
| | Afinion HbA1c Control | 1116793 (MPN 1117475) | 07070060015743 | 7070060HBA000238 |
| | Afinion HbA1c Control | 1117193 (MPN 1117477) | 07070060015767 | 7070060HBA000238 |
| | Afinion HbA1c Calibration Verification | 1117091 | 07070060014999 | 7070060HBA00033A |

Intended Use:

Afinion™ HbA1c

For professional near-patient testing and laboratory use.

For use with the Alere Afinion AS100 Analyzer/Afinion 2 Analyzer.

Afinion HbA1c is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (hemoglobin A1c, HbA1c) in human whole blood. The measure of HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus. This test can be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.

Afinion™ HbA1c Control

For professional near-patient testing and laboratory use.

For use with Afinion HbA1c and Alere Afinion AS100 Analyzer/Afinion 2 analyzer.

Afinion HbA1c Control kit contains liquid preparations of stabilized porcine whole blood (Control C I) and human whole blood (Control C II), respectively. The controls should be used to confirm that your Afinion Analyzer System is working properly and provides reliable results. Only when controls are used routinely, and the values are within acceptable ranges can accurate results for patient samples be assured.

Afinion™ HbA1c Calibration Verification

For professional near-patient testing and laboratory use.

For use with Afinion HbA1c Test and Alere Afinion AS100 Analyzer/ Afinion 2 Analyzer.

Afinion HbA1c Calibration Verification contains liquid preparations of stabilized porcine whole blood and human whole blood. The Afinion HbA1c Calibration Verification materials are to be used with the Afinion Analyzer System to verify the calibration of the Afinion HbA1c test throughout the measurable range.

Classification and rule: Class C, Rule 3(k)

**Common
Specifications:** N/A

Notified Body: BSI Group - The Netherlands B.V
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body No.: 2797

**Conformity
Assessment Route:** Regulation (EU) 2017/746, Annex IX

QMS certificate No.: IVDR 728551

EC Certificate No.: Afinion HbA1c IVDR 728689

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

On behalf of the Manufacturer I hereby declare that the devices listed above fulfil the requirements specified in Regulation (EU) 2017/746 and is in conformity with this Regulation.



Claire Dora
Associate Director, Regulatory Affairs
Abbott Diagnostics Technologies AS



Place/Date (yyyy-mm-dd)