EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 728689 R000

Manufacturer: Abbott Diagnostics Technologies AS

Address:
Kjelsåsveien 161
P.O. Box 6863 Rodeløkka
NO-0504 Oslo
Norway

Single Registration Number: NO-MF-000001423

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-07-05** Date: **2022-07-05** Expiry Date: **2027-07-04**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

AFINION™ HbA1c

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.
For use with the Alere Afinion™ AS100 Analyzer/Afinion™ 2 Analyzer.
For professional near-patient testing and laboratory use.

AFINION™ HbA1c CONTROL

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.
For use with Afinion™ HbA1c Test and Alere Afinion™ AS100 Analyzer/ Afinion™ 2 Analyzer.
For professional near-patient testing and laboratory use.

AFINION™ HbA1c CALIBRATION VERIFICATION

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.
For use with Afinion™ HbA1c Test and Alere Afinion™ AS100 Analyzer/ Afinion™ 2 Analyzer.
For professional near-patient testing and laboratory use.

Risk Classification: Class C near-patient test

Type (Codes as per (EU) 2017/2185): IVR 0602

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Device Name	Model	Basic UDI-DI
AFINION™ HbA1c	1116795 (EUR insert) 1116797 (NOR insert) 1117196 (DE insert)	7070060HBA000136
AFINION™ HbA1c CONTROL	1116793 (Standard insert) 1117193 (DE insert)	7070060HBA000238
AFINION™ HbA1c CALIBRATION VERIFICATION	1117091	7070060HBA00033A

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3204674	Issued

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