# Declaration of Conformity

## Afinion™ ACR

**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 ACR | 1116781 | 07070060013770 | 7070060ACR00015P |
| Afinion ACR | 1116783 | 07070060013817 | 7070060ACR00015P |
| Afinion ACR Control | 1116779 | 07070060013732 | 7070060ACR00025R |

**GMDN:**

| | |
|---|---|
| Afinion ACR | 53479 |
| Afinion ACR Control | 53478 |

**EMDN:**

| | |
|---|---|
| Afinion ACR | W0102160101 |
| Afinion ACR Control | W0101050207 |

**Intended Use:**

AFINION™ ACR

Afinion ACR is an in vitro diagnostic test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine. The measurement of urine albumin, creatinine and ACR aids in the early diagnosis of nephropathy.

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

AFINION™ ACR CONTROL

The Afinion ACR Control kit contains liquid preparations of albumin and creatinine in citrate buffer. 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 obtained are within acceptable ranges can accurate results for patient samples be assured.

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

**Classification and rule:** Class B, Rule 6

**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.:** IVDR 738177

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

Claire Dora
Associate Director, Regulatory Affairs
**Abbott Diagnostics Technologies AS**

Oslo, 2024-09-06

Place/Date (yyyy-mm-dd)

Abbott Diagnostics Technologies AS