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Product Service

# EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

**No. V7 010051 0132 Rev. 03**

**Manufacturer:**

**Abbott GmbH**

Max-Planck-Ring 2  
65205 Wiesbaden  
GERMANY

**Product:**

**Screening test for Hepatitis C marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

**Report No.:**

713177008-2\_28

**Valid from:**

2020-01-28

**Valid until:**

2022-03-31

**Date,**

2020-01-28

Christoph Dicks

Head of Certification/Notified Body



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**No. V7 010051 0132 Rev. 03**

**Model(s):** ARCHITECT Anti-HCV

**Facility(ies):** Abbott GmbH  
Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY

## Parameters:

| Product Name                   | REF N°  |
|--------------------------------|---------|
| ARCHITECT Anti-HCV Reagent Kit | 6C37-22 |
| ARCHITECT Anti-HCV Reagent Kit | 6C37-27 |
| ARCHITECT Anti-HCV Reagent Kit | 6C37-32 |
| ARCHITECT Anti-HCV Reagent Kit | 6C37-37 |
| ARCHITECT Anti-HCV Calibrator  | 6C37-01 |
| ARCHITECT Anti-HCV Controls    | 6C37-10 |
| ARCHITECT Anti-HCV Reagent Kit | 6C37-28 |
| ARCHITECT Anti-HCV Reagent Kit | 6C37-33 |
| ARCHITECT Anti-HCV Reagent Kit | 6C37-38 |
| ARCHITECT Anti-HCV Calibrator  | 6C37-02 |
| ARCHITECT Anti-HCV Controls    | 6C37-15 |
| Anti-HCV Reagent Kit           | 6C37-74 |
| Anti-HCV Reagent Kit           | 6C37-77 |
| Anti-HCV Reagent Kit           | 6C37-78 |
| Anti-HCV Calibrator            | 6C37-09 |
| Anti-HCV Controls              | 6C37-19 |