



# EC Certificate

EC Design-Examination Certificate

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

**No. V7 058438 0014 Rev. 01**

**Manufacturer:**

**AB ANALITICA Srl**

Via Svizzera, 16  
35127 Padova  
ITALY

**Product:**

**NAT-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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V7\\_058438\\_0014\\_Rev.01](http://www.tuvsud.com/ps-cert?q=cert:V7_058438_0014_Rev.01)

**Report No.:**

ITA1886889\_SCN\_V7

**Valid from:**

2022-04-22

**Valid until:**

2025-05-26

**Date,**

2022-04-22

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

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

**No. V7 058438 0014 Rev. 01**

**Model(s):** **AMPLIQUALITY HCV TYPE PLUS**

**Facility(ies):** AB ANALITICA Srl  
 Via Svizzera, 16, 35127 Padova, ITALY

**Parameters:**

Model Name:	Model No.:
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AMPLIQUALITY HCV TYPE PLUS	03-05-20 M (20 tests - manual format)
AMPLIQUALITY HCV TYPE PLUS	03-05-20 A (20 tests - automatic format)
AMPLIQUALITY HCV TYPE PLUS	03-05-XX (5 tests)