



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-245.10.07



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 043136 0045 Rev. 03**

**Manufacturer:** **Abbott Diagnostics Korea Inc.**

65, Borahagal-ro, Giheung-gu  
Yongin-si, Gyeonggi-do 17099  
REPUBLIC OF KOREA

**Product:** **Reagents for determination of infection markers  
for HCV: Anti-HCV Rapid Tests**

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\\_043136\\_0045\\_Rev.03](http://www.tuvsud.com/ps-cert?q=cert:V7_043136_0045_Rev.03)

**Report No.:** 713251529

**Valid from:** 2022-05-10

**Valid until:** 2024-10-17

**Date,** 2022-05-10

Christoph Dicks  
Head of Certification/Notified Body



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**No. V7 043136 0045 Rev. 03**

**Model(s):** Bioline™ HCV

**Facility(ies):** Abbott Diagnostics Korea Inc.  
 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099,  
 REPUBLIC OF KOREA

Abbott Diagnostics Korea Inc.  
 46, Hagal-ro 15beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do  
 17099, REPUBLIC OF KOREA

**Parameters:**

Model Name:	Model No.:
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Bioline™ HCV	02FK10CE, 02FK16CE, 02FK17CE