



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. 00

**Manufacturer:**

**Standard Diagnostics, Inc.**

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

**EC-Representative:**

MT Promedt Consulting GmbH  
Altenhofstrasse 80, 66386 St. Ingbert, GERMANY

**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. See also notes overleaf.

**Report No.:**

713139439

**Valid from:**

2018-09-25

**Valid until:**

2023-02-14

**Date,**

2018-09-25

Stefan Preiß



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# EC Certificate

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No. V7 043136 0045 Rev. 00

**Model(s):**

**SD BIOLINE HCV**

**Facility(ies):**

Standard Diagnostics, Inc.  
65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099,  
REPUBLIC OF KOREA

Standard Diagnostics, 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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SD BIOLINE HCV

02FK10CE, 02FK16CE, 02FK17CE