



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. 02

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. See also notes overleaf.

Report No.:

713182857-2

Valid from:

2020-05-05

Valid until:

2023-02-14

Date,

2020-05-05

C.D.H

Christoph Dicks
Head of Certification/Notified Body



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



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No. V7 043136 0045 Rev. 02

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