



Declaration of Conformity

IVDD 98/79/EC

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Manufacturer Abbott Diagnostics Korea Inc.
65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,
17099 Republic of Korea

European Representative MT Promedt Consulting GmbH
Altenhofstrasse 80 66386 St. Ingbert Germany

Product Designation Bioline™ HCV

EDMS Code 15 70 02 02 00 [HCV Antibody – Rapid Test]

Catalogue No. 02FK10CE, 02FK16CE, 02FK17CE

Classification List A ; Annex II IVD

EC Certificate No. V7 043136 0045 Rev. 02
V1 043136 0056 Rev. 00

Conformity Assessment Route Annex IV, item 4 Applied (IVDD 98/79/EC)

We herewith declare that above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Standard Applied List of (Harmonized) standards for which documented evidence for compliance can be provided.
* EN ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes
(ISO 13485:2016) DIN EN ISO 13485:2016
Certificate No. : Q5 043136 0055 Rev. 00

Start of CE marking Feb. 19, 2018

Date of Issue Jul. 02, 2020

On the behalf of
Abbott Diagnostics Korea Inc.

Signature
Jung, Jae-Ho
Site Director