Declaration of Conformity

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

Digitally signed by Bolea Petru
Date: 2021.09.27 14:10:16 EEST
Reason: MoldSign Signature
Location: Moldova