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 D-66386 St. Ingbert Germany
Product Designation	Bioline™ HIV 1/2 3.0 Product group
EDMA Code	15 70 03 02 00 [HIV 1/2 Rapid Test]
Catalogue No.	03FK10CE, 03FK10LCE, 03FK16CE 03FK18CE, 03FK11CE
Classification	List A ; Annex II IVD
EC Certificate No.	V7 043136 0046 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	Oct. 09, 2008
Date of Issue	Jul. 02, 2020

Digitally signed by Bolea Petru
Date: 2021.09.27 14:13:27 EEST
Reason: MoldSign Signature
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On the behalf of
Abbott Diagnostics Korea Inc.

Signature

Jung, Jae-Ho
Site Director