



Abbott Diagnostics Korea Inc.
65, Borahagal-ro,,
Giheung-gu, Yongin-si,
Gyeonggi-do, Republic of Korea (17099)
Tel: +82.31.899.2800
Fax: +82.31.899.2840

DECLARATION OF CONFORMITY

Name and address of Manufacturer

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

We, Abbott Diagnostics Korea Inc., hereby confirm that we have established and is maintaining a quality management system, which meets the below standard applied.

1) Particulars of medical device include: –

- a. Manufacturer: Abbott Diagnostics Korea Inc.
- b. Country of origin: Republic of Korea
- c. Manufacturing site: 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099, Republic of Korea

| No. | Product name | Cat No. |
|-----|-------------------|---------|
| 1 | Bioline™ HBsAg WB | 01FK10W |



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2) Quality management system (QMS) certificate:

- a. Conformity assessment body issuing the certificate: TÜV SÜD Product Service GmbH
- b. Certificate number: Q5 043136 0055 Rev. 00
- c. Issuance date: 2020-05-22
- d. Expiry date: 2022-08-31

3) Standards applied:

EN ISO 13485:2016
Medical devices- Quality management systems-
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

This declaration of conformity is valid from June 03, 2021.

Signature:

Abbott Diagnostics Korea Inc

A handwritten signature in blue ink, appearing to read 'Jung, Jaeho', written over a horizontal blue line.

Jung, Jaeho
Site Director



Jung, Jae ho
Site Director
Abbott Diagnostics Korea Inc.