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 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
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 ZLG-BS-245.10.07



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 0046 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 HIV-1/HIV-2: Anti-HIV-1/HIV-2 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:** 2023-10-06

**Date,** 2020-05-05

Christoph Dicks  
 Head of Certification/Notified Body

