ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD 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 001922 0009 Rev. 01

Manufacturer: **Abbott Ireland Diagnostics Division**
Finisklin Business Park
Sligo
IRELAND

Product: **Screening and Confirmatory Test for Hepatitis B marker**

Model(s): **ARCHITECT HBsAg Qualitative II**
ARCHITECT HBsAg Qualitative II Confirmatory

Parameters:

Product Name	REF N°
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-30
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-35
ARCHITECT HBsAg Qualitative II Calibrators	2G22-01
ARCHITECT HBsAg Qualitative II Controls	2G22-10
ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit	2G23-25

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 001922 0009 Rev. 01

Report No.: 713190856-2

Digitally signed by Ceaicovschi Tudor
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Reason: MoldSign Signature
Location: Moldova

Valid from: 2021-05-26
Valid until: 2024-05-26

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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