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Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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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. 00

**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. See also notes overleaf.

**Report No.:** 713155489-2\_08

**Valid from:** 2019-03-30

**Valid until:** 2021-05-25

**Date,** 2019-03-29

Stefan Preiß

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

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