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