



EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 010283 0610 Rev. 05

Manufacturer: **Roche Diagnostics GmbH**

Sandhofer Strasse 116

68305 Mannheim

GERMANY

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

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_010283_0610_Rev.05

Report No.: 713237302-02_SCN

Valid from: 2022-04-27

Valid until: 2025-05-07

Date, 2022-04-27

Christoph Dicks

Head of Certification/Notified Body



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Model(s): Elecsys HBsAg II
 PreciControl HBsAg II
 Elecsys HBsAg Confirmatory Test
 Elecsys HBsAg II Auto Confirm
 PreciControl HBsAg Auto Confirm
 Elecsys and cobas e analyzers

Facility(ies): Roche Diagnostics GmbH
 Nonnenwald 2, 82377 Penzberg, GERMANY

Roche Diagnostics GmbH
 Sandhofer Strasse 116, 68305 Mannheim, GERMANY

Roche Diagnostics International Ltd
 Forrenstrasse 2, 6343 Rotkreuz, SWITZERLAND

Parameters:	Model Name:	Model No.:
	Elecsys HBsAg II	04687787190
		08814856190
	Elecsys HBsAg II	07914482190
		08814864190
	Elecsys HBsAg II	07251076190
		08814848190
	PreciControl HBsAg II	04687876190
	Elecsys HBsAg Confirmatory Test	11820648122
		09127127190
	Elecsys HBsAg II Auto Confirm	08741034190
	PreciControl HBsAg Auto Confirm	08741107190
	Elecsys and cobas e analyzers	