



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 0630 Rev. 03

Manufacturer: Roche Diagnostics GmbH

Sandhofer Strasse 116
68305 Mannheim
GERMANY

Product: Screening test for Hepatitis C 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_0630_Rev.03

Report No.: 713237302-02_SCN

Valid from: 2022-04-27

Valid until: 2025-05-26

Date, 2022-04-27

Christoph Dicks
Head of Certification/Notified Body



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



Product Service

EC Certificate

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No. V7 010283 0630 Rev. 03

Model(s): Elecsys Anti-HCV II
 PreciControl Anti-HCV
 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 Anti-HCV II	06368921190
	Elecsys Anti-HCV II	06427405190
	Elecsys Anti-HCV II	07026889190
	Elecsys Anti-HCV II	08836981190
	Elecsys Anti-HCV II	08837031190
	Elecsys Anti-HCV II	08837058190
	PreciControl Anti-HCV	03290379190
	Elecsys and cobas e analyzers	