



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 0613 Rev. 03

Manufacturer:

Roche Diagnostics GmbH

Sandhofer Strasse 116
68305 Mannheim
GERMANY

Product:

Screening test for HIV-1/-2 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_0613_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



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 0613 Rev. 03

Model(s): Elecsys HIV Duo
 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 HIV Duo	07229542190 08836973190
	Elecsys and cobas e analyzers	