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Verification Report

according to Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices – Annex IX, sec. 4.12 or Annex XI sec. 5

No. ROC-09014977190 26 03 077749

Manufacturer: **ROCHE Diagnostics GmbH**
Sandhofer Strasse 116
D-68305 Mannheim

Product: **Elecsys Syphilis**

Testplan: **TP-ROC-09014977190**

Batch: **93077101**

Basic UDI-DI:

Expiry Date: **28.02.2027**

Mat-Nr.: 09015051190
Syphilis Elecsys E2G 300
Batch: 93077101
2~ 8°C 
Lot: 040016684768 03.03.2026
Sample No./Type: 216042742/Y2

The above mentioned batch meets the batch release criteria established during technical documentation assessment and may be placed on the market. The design examination certificate issued for this product is V70 010283 0695 Rev. 02.

Matilde C.V. Nagel

Date, 2026-03-04

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Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAGfIoTnzEJuRyZa_VrKJcz5KwMqDY

pp Dr. Matilde Calado Vieira Nagel
In-vitro Diagnostics

TÜV SÜD Product Service GmbH is Notified Body according to Council Vitro Diagnostic Regulation 2017/746 concerning In-vitro Diagnostic Medical Devices with Identification No. 0123.

To:

ROCHE Diagnostics GmbH
Dr. Sonja Leyrer
+49 8856 6016175

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG - BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
In-vitro Diagnostics
Ridlerstrasse 65
80339 Munich
Germany

tuvsud.com/ps
Phone: +49 89 50084-483
Fax: +49 89 50084-475

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