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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 25 12 076433

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

Product: **Elecsys Syphilis**

Mat-Nr.: 09015051190
Syphilis Elecsys E2G 300
Batch: 91165901
2 - 8°C
Lot: 040016099865 15.12.2025
Sample No./Type:215471865/Y2

Testplan: **TP-ROC-09014977190**

Batch: **91165901**

Basic UDI-DI:

Expiry Date: **30.11.2026**

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, 2025-12-18

{{BigSig_es_:signer1:signature:dimension(width=60mm, height=10mm)}}
Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAraWXswNeDD4fVZX9Bc878W62di7T7zik
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:
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