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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 11 075961

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

Product: **Elecsys Syphilis**

Testplan: **TP-ROC-09014977190**

Batch: **91168201**

Basic UDI-DI:

Expiry Date: **31.10.2026**

Mat-Nr.: 09014977190
Syphilis Elecsys cobas e
Batch: 91168201
2 - 8°C
Lot: 040015871803 17.11.2025
Sample No./Type:215595142/Y2

The above mentioned batch meets the batch release criteria established during technical documentation assessment and may be placed on the market. The EU Technical Documentation Assessment Certificate (IVDR) issued for this product is V70 010283 0695 Rev. 02.

Date, 2025-11-25

Simone Findling
Simone Findling (25. November 2025 18:44:11 GMT+1)
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pp Dr. Simone Findling
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