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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 078008

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

Product: **Elecsys Syphilis**

Mat-Nr.: 09014977190
Syphilis Elecsys cobas e
Batch: 93076201
2 ~ 8 °C
Lot: 040016791686 13.03.2026
Sample No./Type:216148082/Y2

Testplan: **TP-ROC-09014977190**

Batch: **93076201**

Basic UDI-DI:

Expiry Date: **31.01.2027**

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.

Date, 2026-03-18

Alexandra Asbach-Nitzsche
Alexandra Asbach-Nitzsche (19. März 2026 10:23:06 GMT+1)
Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAjK3i1hWW1Ah2UT1X9MsJEnfP7m9
pp Dr. Alexandra Asbach-Nitzsche
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.

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