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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-090203095 25 11 075780

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


Product: **Elecsys Anti-SARS CoV-2**

Testplan: **TP-ROC-09203095**

Batch: **90644401**

Basic UDI-DI:

Expiry Date: **30.04.2026**

Mat-Nr.: 09203079190
Anti-SARS-CoV-2 Elecsys E
Batch: 90644401
2~ 8°C 
Lot: 040015737110 21.10.2025
Sample No./Type: 215112289/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 0657 Rev. 01.

REF ID: 09203079190

Date, 2025-11-18

Alexandra Asbach-Nitzsche

Alexandra Asbach-Nitzsche (18. November 2025 10:52:09 GMT+1)

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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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