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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-06427405 25 10 075406

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

**Product:** **Elecsys Anti-HCV II**

**Testplan:** **TP-ROC-06427405**

**Batch:** **91396804**

**Basic UDI-DI:**

**Expiry Date:** **28.02.2027**

Mat-Nr.: 08837058192  
Anti-HCV G2 Elecsys E2G 1  
Batch: 91396804  
2~ 8°C   
Lot: 040015470439 13.10.2025  
Sample No./Type:214860108/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 0679 Rev. 02.

Ref ID#08837058190

**Date,** 2025-10-29

Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAYFGnbWkmgynwBi0tEtGUxuhHQ0QQxY3

pp Patrick Unverzagt  
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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Information pursuant to § 2 [1] DL-InfoV

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