



Add value.
Inspire trust.

Verification Report

according to Directive 98/79/EC Annex IV.6

No. ROC-04687787 25 08 073934

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

Product: **Elecsys HBsAg II**

Mat-Nr.: 08814856190
HBsAg G2 Elecsys cobas e
Batch: 86386301
2~ 8°C 
Lot: 040013888074 22.07.2025
Sample No./Type: 212906534/Y2

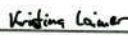
Batch: **86386301**

Expiry Date: **31.12.2026**

The above mentioned batch meets the batch release criteria established during design examination and may be placed on the market. The design examination certificate issued for this product is V7 010283 0610 Rev. 05.

Ref ID: 08814856190

Date, 2025-08-06


Kristina Laimer (6. August 2025 13:25:59 GMT+2)
Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAA1nTbzGjUPDzo7wgd3a3mP7kGUSy5sFXA
i.A. Dr. Kristina Laimer
In-vitro Diagnostics

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 98/79/EC concerning In-vitro Diagnostic Medical Devices with Identification No. 0123.

To:
ROCHE Diagnostics GmbH
Dr. Sonja Leyrer
+49 8856 6016175

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
In-vitro Diagnostics
Ridlerstrasse 65
80339 Munich
Germany

tuvsud.com/ps
Phone: +49 89 50084-483
Fax: +49 89 50084-475

TÜV®