



Product Service

Verification Report

according to Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices – Annex IX, sec. 4.12 or Annex XI sec. 5

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No. ROC-07374160 23 10 065200

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

Product: **Elecsys Anti-HBc II**

Testplan:

Batch: **74175201**

Full UDI:

Expiry Date: **31.08.2024**

Mat-Nr.: 09014926190
Anti-HBc G2 Elecsys E2G 3
Batch: 74175201
2 ~ 8 °C
Lot: 040004206110 18.09.2023
Sample No./Type: 203211963/Y2

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 0626 Rev. 03.

Date, 2023-10-05

Lubov Delamotte (5. Oktober 2023 14:27 GMT+2)

Adobe Acrobat Sign-Transaktionsnummer: CBJCH8CAABAACLKWAQVgUDSkNdQuA54_c4thdmwdg5Cm

i.A. Lubov Delamotte
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

Headquarters: Munich
Trade Register Munich HRB 85742
V.A.T. DE 129484267
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
Information pursuant to § 2 [1] DL-InfoV

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:

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

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