Product Service

Add value.
Inspire trust.

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-09318402190 23 11 065555

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

Product: **Elecsys HBeAg quant**

Mat-Nr.: 09318399190
HBeAg quant Elecsys E2G 3
Batch: 73339101
2 ˚ 8 °C
Lot: 040003581106 21.08.2023
Sample No./Type:202644400/Y2

Testplan: **TP-ROC-09318402190**

Batch: **73339101**

Full UDI:

Expiry Date: **30.04.2024**

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 0682 Rev.00.

Date, 2023-11-02

Lubov Delamotte (2. November 2023 17:40 GMT+1)
Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAddHkRs-cXkrbc5j-LXJtoSD6H8mh-EhT
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

cc: