



Product Service

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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-09318402190 23 11 065555

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

Product: Elecsys HBeAg quant

Testplan: TP-ROC-09318402190

Batch: 73339101

Full UDI:

Expiry Date: 30.04.2024

Mat-Nr.: 09318399190
HBeAg quant Elecsys E2G 3
Batch: 73339101
2-8°C
Lot: 040003581106 21.08.2023
Sample No./Type: 202644400/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 0682 Rev.00.

Date, 2023-11-02

Lubov Delamotte (2. November 2023 17:40 GMT+1)

Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAddHkRs-cXkrbcSj-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:

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cc:

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