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-07374160 23 10 065200

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

Product: **Elecsys Anti-HBc II**

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

Testplan:

Batch: **74175201**

Full UDI:

Expiry Date: **31.08.2024**

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: CBJCHBCAABAACLKWAQVgUDSkNdQuA54_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:
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