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Verification Report

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

No. ROC-04687787 25 03 071642

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

Product: **Elecsys HBsAg II**

Mat-Nr.: 08814856190
HBsAg G2 Elecsys cobas e
Batch: 83497603
2~8°C

Batch: **83497603**

Lot: 040008758003 25.02.2025
Sample No./Type: 206756795/Y2

Expiry Date: **31.08.2026**

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.

Matilde C V Nagel

Date, 2025-03-04

{{BigSig_es;signer1:signature:dimension(width=60mm, height=10mm)}}
Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAUCHfiiuoXKry0JLJSgh2324o_J4XV7S
i.A. Dr. Matilde Calado Vieira Nagel
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.

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