



Product Service

Verification Report

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

Add value.
Inspire trust.

No. ROC-04687787 22 12 061724

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

Product: Elecsys HBsAg II
Elecsys and cobas e analyzers

Mat-Nr.: 08814864190
HBsAg G2 Elecsys cobas e
Batch: 67749801
2~8°C
Lot: 040001436396 30.11.2022
Sample No./Type: 201061143/Y2

Batch: 67749801

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 0610 Rev. 05.

Date, 2022-12-15

A. Ait Benarrou

Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAI7GIQ0E4kAfYnKi8XdhCRegQhTNPJ-q

i.A. Ahmed Ait Benarrou
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.

To:

ROCHE Diagnostics GmbH
Dr. Rainer Bäuerlein
08856 / 60-3647

cc: PEI-IVD, FAX +49 6103 77123

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
(Germany) at www.tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

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

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