

## **Amendment to IVDD EC Declaration of Conformity**

*pursuant to Article 110 (3) of EU 2017/746 (IVDR) concerning in vitro diagnostic medical devices*

**Manufacturer:** Roche Diagnostics GmbH

**Address:** Sandhofer Strasse 116  
68305 Mannheim  
Germany

*This amendment is only valid in combination with the following EC Declaration of Conformity (IVDD):*

**Product Name: Elecsys HBsAg II**

**Cat. No.:**  
**08814848190**

**Signed on: 15-Feb-2021**

*This Amendment confirms the validity of the aforementioned EC Declaration of Conformity (IVDD).  
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.*

**Description of change:**

Addition of a new catalogue number 08814848192 for a new package size (“multi pack/maxi pack”) of the product Elecsys HBsAg II.

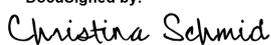
**Intended Use:**

Immunologischer In-vitro-Test zur qualitativen Bestimmung von Hepatitis-B Oberflächenantigen (HBsAg) in Humanserum und -plasma.  
Der ElektroChemilumineszenz ImmunoAssay “ECLIA“ ist zur Durchführung an cobas e Immunoassay-Systemen vorgesehen.  
Immunoassay for the in vitro qualitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma.  
The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Mannheim, 18 August 2023

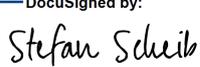
Roche Diagnostics GmbH

*i.V./on behalf of the company*

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