

## **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 Anti-HCV II**

**Cat. No.:**  
**08836981190**  
**08837031190**  
**08837058190**

**Signed on: 09-Feb-2022**

*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 08837058192 for a new package size (“multi pack/maxi pack”) of the product Elecsys Anti-HCV II.

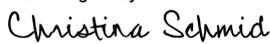
**Intended use:**

Der Elecsys Anti-HCV II Test ist ein diagnostischer In-vitro-Test für den qualitativen Nachweis von Antikörpern gegen Hepatitis-C-Virus (HCV) in Humanserum und -plasma.  
Der ElektroChemilumineszenz ImmunoAssay “ECLIA“ ist zur Durchführung an cobas e Immunoassay-Systemen vorgesehen.  
The Elecsys Anti-HCV II assay is an in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma.  
The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Mannheim, 2 August 2023

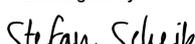
Roche Diagnostics GmbH

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

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