

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

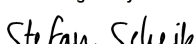
i.V./on behalf of the company

DocuSigned by:

E3965E80F3E840E...

Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab



Contact address:

Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim