

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 HIV Duo

Cat. No.: 08836973190

Signed on: 04-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 08836973192 for a new package size (“multi pack/maxi pack”) of the product Elecsys HIV Duo.

Intended use:

Immunologischer In-vitro-Test zur qualitativen Bestimmung von HIV-1 p24-Antigen und Antikörpern gegen HIV-1, einschließlich Gruppe O, und HIV-2 in Humanserum und -plasma. Die Einzelergebnisse (HIV Ag und Anti-HIV) dienen als Hilfe bei der Auswahl des Bestätigungsalgorithmus für reaktive Proben.

Der ElektroChemilumineszenz ImmunoAssay “ECLIA“ ist zur Durchführung an cobas e Immunoassay-Systemen vorgesehen.

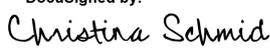
Immunoassay for the in vitro qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma. The subresults (HIV Ag and anti-HIV) are intended as an aid in the selection of the confirmation algorithm for reactive samples.

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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