

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: PreciControl HBsAg II

Cat. No.: 04687876190

Signed on: 26 August 2020

*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:

Removal of “Elecsys” from intended use as per current package insert.

Updated intended use:

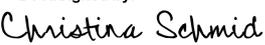
PreciControl HBsAg II is used for quality control of the Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm immunoassays on **cobas e** immunoassay analyzers.

PreciControl HBsAg II dient zur Qualitätskontrolle der Elecsys HBsAg II und Elecsys HBsAg II Auto Confirm Immunoassays auf **cobas e** Immunoassay – Analyzern.

Mannheim, 4 May 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

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