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Verification Report

according to Directive 98/79/EC Annex IV.6

No.

ROC-11820583 13 01 025728

Manufacturer:

ROCHE Diagnostics GmbH

Nonnenwald 2

D-82377 Penzberg

Product:

HBeAg

Elecsys and cobas e analyzers

Batch:

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17108002

Expiry Date:

08-2014

The above mentioned batch meets the batch release criteria established during design examination and may be placed on the market. The design examination certificate issued for this product is V7 12 07 10283 270.

Date, 2013-01-28

i.A. Dr. Christine Pottgießer In-vitro-Diagnostik

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices with Identification No. 0123.

To (via Telefax):

ROCHE Diagnostics GmbH Dr. Ingo Krüger 08856 / 60-3647 ¢c: ---

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