

Mat-Nr.: 11820583122
 HBeAg Elecsys cobas e 100
 Batch: 25230004
 2-8°C
 Lot: 040000183609 29.09.2017
 Sample No./Type:200126979/Y2



Verification Report

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

No. ROC-11820583 17 10 040008

Manufacturer: ROCHE Diagnostics GmbH
 Sandhofer Strasse 116
 D-68305 Mannheim

Product: HBeAg
 Elecsys and cobas e analyzers

Batch: 25230004

Expiry Date: 02-2019

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 16 11 10283 376.

Date, 2017-10-27

V. Schlüter
 i.A. Dr. Volker Schlüter
 In-vitro-Diagnostika

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. Rainer Bäuerlein
 08856 / 60-3647

CC: ---

Headquarters: Munich
 Trade Register Munich
 HRB 85742
 V.A.T. DE 129484267
 UniCredit Bank AG
 BIC HYVEDEMMXXX
 IBAN DE13 7002 0270 0048 8522 11

Geschäftsführer:
 Robert Kees (Spracher)
 Dr. Jens Butenandt

Tel.: +49 89 5008-4483
 Fax: +49 89 5008-4475
 www.tuev-sued.de
 TÜV®

TÜV SÜD Product Service GmbH
 In-vitro-Diagnostika
 Rüdlerstraße 65
 80339 München
 Germany