

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV SÜD Product Service GmbH (Ridlerstraße 65, 80339 München, Germany) als Notified Body (Nr. 0123)

as per Annex IV of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998 via TÜV SÜD Product Service GmbH (Ridlerstrasse 65, 80339 Munich, Germany) as the Notified Body (No. 0123)

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **HTLV-I/II**

Art.-Nr./Cat. No.: **07091656**
07173032

Beschreibung/Description: Immunologischer In-vitro-Test zur qualitativen Bestimmung von HTLV-I/II-Antikörpern in Humanserum und -plasma. Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen./
*Immunoassay for the in vitro qualitative determination of antibodies to HTLV-I/II in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.*

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostika entspricht.

to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 08 June 2015

Roche Diagnostics GmbH

ppa./on behalf of the company

A blue ink signature of Dr. Peter Martin, featuring a large, stylized loop at the beginning and a long, horizontal stroke extending to the right.

Dr. Peter Martin
Senior Director Global Regulatory Affairs
Roche Professional Diagnostics

ppa./on behalf of the company

A blue ink signature of Ralf Zielenski, written in a cursive style with several loops and a long horizontal stroke at the end.

Ralf Zielenski
Head of Quality
Roche Professional Diagnostics

Kontaktadresse/*Contact address*: Roche Diagnostics GmbH
Abt./*Dept.* Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim