

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 *as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998*

Hersteller/Manufacturer: Hitachi High-Tech Corporation
1-17-1 Toranomon, Minato-ku
Tokyo 105-6409
Japan

Authorized Representative: Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

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

Produktname / <i>Product name:</i>	Art.-Nr./ <i>Id. No.:</i>	Ab Serien-Nr. / <i>Starting with Serial No.</i>
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cobas e 801 analytical unit	08454345001	1801-01
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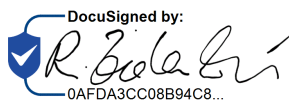
Beschreibung/Description: Fully automated, random-access, software controlled analytical unit for immunoassay analysis intended for qualitative and quantitative in-vitro determinations using a wide variety of tests.

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.
to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 18 June 2018

Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company
i.V. Dr. Joachim Hoch

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Dr. Stefan Scheib
Director Global Regulatory Affairs
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