



## **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 Parliaments and Council of 27 October 1998*

Hersteller/Manufacturer:

Hitachi High-Technologies Corporation  
Headquarter:  
1-24-14 Nishi-Shimbashi, Minato-ku Tokyo 105-8717, Japan

Manufacturing site (*all system components*):  
Hitachi High-Technologies Corporation  
882 Ichige Hitachinaka-shi, Ibaraki-ken, 312-8504, Japan

Manufacturing site (*core unit only*):  
Hitachi Instrument (Suzhou), Ltd.  
No. 137, Fangzhong Street, Suzhou Industrial Park, 215025 Suzhou, China

Authorized Representative:

Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)  
*Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)*

Produktname/Product name:

**cobas<sup>®</sup> 6000 system**

Art.-Nr./Id. No.:

See list of **cobas<sup>®</sup> 6000 system components**

Beschreibung/Description:

The cobas 6000 analyzer series is a fully automated system for immunological and clinical chemistry analysis intended for the in vitro quantitative/qualitative determination of analytes in body fluids.

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-Diagnostica 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, 05 November 2014

Roche Diagnostics GmbH  
*ppa./on behalf of the company*

*i.v.*  


Dr. Michael Thein  
Head of Quality  
Roche Professional Diagnostics

*ppa./on behalf of the company*



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

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Sandhofer Strasse 116  
68305 Mannheim  
Germany



Liste der **cobas® 6000** Systemkomponenten/  
*List of cobas® 6000 system components:*

Produktname/ *Product Name*

Art. Nr./ *Id. No.*

**cobas® 6000** core unit

04745868 001 (*HHT Japan*)

07339496 001 (*HIS China*)

**cobas® c 501** module

04745914 001

**cobas® e 601** module

04745922 001

Varianten/ *Variants*

Art. Nr./ *Id. No.*

**cobas® c 501** + core

See Art. No's of single components

**cobas® e 601** + core

See Art. No's of single components

**cobas® c 501** + **cobas® c 501** + core

See Art. No's of single components

**cobas® c 501** + **cobas® e 601** + core

See Art. No's of single components

**cobas® e 601** + **cobas® e 601** + core

See Art. No's of single components

**cobas® c 501** + **cobas® c 501** + **cobas® e 601** + core

See Art. No's of single components

**cobas® c 501** + **cobas® e 601** + **cobas® e 601** + core

See Art. No's of single components

Optionale Komponenten/ *Optional Components:*

Komponentenname/ *Component Name*

Art. Nr./ *Id. No.*

**cobas® 6000** c-connection

04745876 001

**cobas® 6000** c-extension

04885775 001

**cobas® 6000** e-extension

04885783 001

**cobas® 6000** 2nd rotor

04952324 001