



## **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-Technologies Corporation  
1-24-14 Nishi-Shimbashi, Minato-ku  
Tokyo 105-8717  
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/Product name: **cobas® 8000 modular analyzer series**

Art.-Nr./Id. No.: siehe Seite 2 / *see page 2*

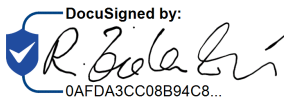
Beschreibung/Description: The **cobas® 8000** modular analyzer series is a fully automated, random-access, software controlled system for immunoassay and photometric analysis intended for qualitative and quantitative in-vitro determinations using a wide variety of tests.

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, 16 Februar 2021

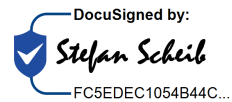
Roche Diagnostics GmbH

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

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Dr. Stefan Scheib  
Director Global Regulatory Affairs  
Centralised and Point of Care Solutions

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



Liste der **cobas**<sup>®</sup> 8000 Systemkomponenten /  
*List of **cobas**<sup>®</sup> 8000 system components:*

| Produktname /<br><i>Product Name</i> | Produkt Art. Nr. /<br><i>Product Id. No.</i> |
|--------------------------------------|--|
| <b>cobas c</b> 502 Module            | 05964067001                                  |
| <b>cobas e</b> 602 Module            | 05990378001                                  |

Liste der optionalen Komponenten /  
*List of Optional Components:*

| Komponentenname /<br><i>Component Name</i> | Art. Nr. /<br><i>Id. No.</i> |
|--|------------------------------|
| cobas 8000 ISE Support Box                 | 08126232001                  |