

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
und/and

gemäß Anhang VI der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011
as per Annex VI of Directive 2011/65/EU of the European Parliament and Council of 8 June 2011

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: 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® 6800 System**

Art.-Nr./Cat. No.: **05524245001**

Including:

06301037001: Sample Supply Module
06379672001: **cobas®** 6800 System movable Platform
06379664001: **cobas®** 6800 System fixed Platform
06349595001: Instrument Gateway
08399786001: SW **cobas®** 6800/8800 version 1.3.8
08399808001: SW **cobas®** 6800/8800 LP *Language Package* version 1.3.8
08399794001: SW **cobas®** 6800/8800 MP *Maintenance Package* version 1.3.8
08315213001: SW Patch **cobas®** 6800/8800 version 1.2.13
08051283001: SW **cobas®** 6800/8800 version 1.2.12
08051291001: SW **cobas®** 6800/8800 MP *Maintenance Package* version 1.2.12
08051305001: SW **cobas®** 6800/8800 LP *Language Package* version 1.2.12
07830556001: SW **cobas®** 6800/8800 version 1.1.10
07886837001: SW **cobas®** 6800/8800 MP *Maintenance Package* version 1.1.10
07830564001: SW **cobas®** 6800/8800 LP *Language Package* version 1.1.10
07541970001: SW **cobas®** 6800/8800 version 1.1.9
07704437001: SW **cobas®** 6800/8800 MP *Maintenance Package* version 1.9.10
07704445001: SW **cobas®** 6800/8800 LP *Language Package* version 1.1.9.
07521626001: SW SSM 003.0006.0112

Beschreibung/Description:

The **cobas**[®] 6800 System is designed to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT) to be applied in diagnostic and blood screening laboratories. Each Analytic System is comprised of a Sample Supply Module, which loads and unloads sample tubes to and from the Transfer Module; a Transfer Module, which pipettes samples from the sample tubes in processing plates; one **cobas**[®] 6800 Processing Module, which performs sample preparation and nucleic acid extraction; and one **cobas**[®] 6800 Analytic Module, which performs real-time PCR on the processed samples. The **cobas**[®] 6800 System also includes the system software and the Instrument Gateway Server.

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-Diagnostika (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).

und/and

Ab Serien-Nr./Starting with
Serial No.:

1275

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 2011/65/EU inklusive Artikel 4 des Europäischen Parlaments und des Rates vom 8. Juni 2011 betreffend Beschränkung der Verwendung bestimmter gefährlicher Stoffe gemäss Anhang II (Blei, Quecksilber, Cadmium, Sechswertiges Chrom, Polybromierte Biphenyle and Polybromierte Diphenylether) in Elektro- und Elektronikgeräten (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

to which this declaration relates fulfills the requirements of Directive 2011/65/EU including Article 4 of the European Parliament and Council of 8 June 2011 on the restriction of the use of certain hazardous substances according Annex II (lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyls and polybrominated diphenyl ethers) in electrical and electronic equipment (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, 6 December 2017

Roche Diagnostics GmbH

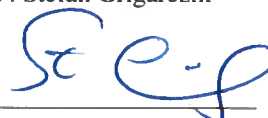
ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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i.V. Stefan Grigarczik



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