



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: Roche Diagnostics GmbH
Adresse/Address: Roche Professional Diagnostics
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 b 123 <1> POC system**
Art.-Nr./Id. No.: 05122244001

Produktname/Product name: **cobas b 123 <2> POC system**
Art.-Nr./Id. No.: 05122252001

Produktname/Product name: **cobas b 123 <3> POC system**
Art.-Nr./Id. No.: 05122279001


Produktname/Product name: **cobas b 123 <4> POC system**
Art.-Nr./Id. No.: 05122287001

Beschreibung/Description: The **cobas b 123** POC system is a fully automated Point of Care (POC) system for in vitro measurements of pH, blood gases (BG), electrolytes (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O₂Hb, HHb, COHb), oxygen saturation (SO₂) and neonatal bilirubin (Bili). In addition the **cobas b 123** POC system calculates derived parameters. It is dedicated for use in a POC environment and laboratory. The integrated AutoQC module and the oximeter module are available as an option.

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, 06-Dec-2013

Roche Diagnostics GmbH
ppa./on behalf of the company



Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

Roche Diagnostics International Ltd
ppa./on behalf of the company



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