

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 Fluid Pack 200
Art.-Nr./Id. No.: 05403308001

cobas b 123 Fluid Pack 400
05403154001

cobas b 123 Fluid Pack 700
05403286001

cobas b 123 Fluid Pack COOX 200
05169992001

cobas b 123 Fluid Pack COOX 400
05170036001

cobas b 123 Fluid Pack COOX 700
05170052001

Beschreibung/Description: The cobas b123 Fluid Packs are an accessory to the cobas b123 POC system.
The cobas b123 POC system is a fully automated POC system for in vitro measurement of pH, blood gases (BG), electrolytes (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O2Hb, HHb, COHb, MetHb), oxygen saturation (SO2) and neonatal bilirubin (Bili).

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, *26. Sep. 2013*
Roche Diagnostics GmbH
ppa./on behalf of the company



Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

Rotkreuz, *26. Sep. 2013*
Roche Diagnostics International Ltd
ppa./on behalf of the company



Ralf Zielenski
Head of Quality GPS and RDI
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