



## 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

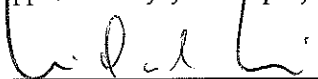
Hersteller/Manufacturer: Roche Diagnostics GmbH  
Adresse/Address: Roche Professional Diagnostics  
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Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten) Roche Diagnostics GmbH declares that the product/the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

Produktname/Product name: CoaguChek XS® Pro  
Art.-Nr./Id. No.: 04837975001  
Beschreibung/Description: The CoaguChek XS® Pro system (CoaguChek XS Pro meter and CoaguChek XS PT Test strip) quantitatively determines prothrombin time ("PT"), using capillary blood or whole blood from a vein (nonanticoagulated venous whole blood). It is indicated for use by healthcare professionals. The system is ideally suited to monitor coagulation values in people who are taking oral anticoagulation medication (vitamin K antagonists, VKAs).

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, 19.10.2009

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