

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
Sandhofer Straße 116
D-68305 Mannheim

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: **Immunoglobulin A**

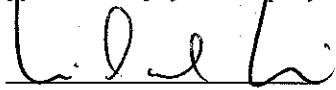
Art.-Nr./Id. No.: **20737755**

Beschreibung/Description:

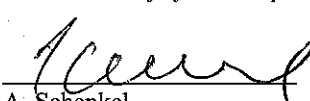
In-vitro-Test zur quantitativen immunologischen Bestimmung von Human-Immunoglobulin A in Serum und Plasma mit COBAS INTEGRA Systemen. Neben der Standardapplikation (Test IGA, Test-ID 0-075) gibt es eine sensitive Applikation (Test IGAP, Test-ID 0-175), die zur quantitativen Bestimmung geringer IgA-Konzentrationen, z.B. in pädiatrischen Proben, dient.
In vitro test for the quantitative immunological determination of human immunoglobulin A in serum and plasma on COBAS INTEGRA systems. In addition to the standard application (test IGA, test ID 0-075), the sensitive application (test IGAP, test ID 0-175) is designed for the quantitative determination of low IgA concentrations in e.g. pediatric samples.

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, 10. August 2011
Roche Diagnostics GmbH
i. V. / on behalf of the company


Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

i. V. / on behalf of the company


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