

CERTIFICATE

Number: 2112853DE01



EC DESIGN-EXAMINATION IN VITRO DIAGNOSTIC MEDICAL DEVICES

Issued to:

Health-Chem Diagnostics LLC
3341 SW 15 Street
Pompano Beach, FL 33069
USA

For the product(s) / product category (s):


Solid Phase Immunoassay for the Detection of Human Chorionic Gonadotrophin (hCG) in Urine

Documents that form the basis of this certificate:

Certification Notice 2112853CN, initially dated August 1, 2008
Addendum, initially dated August 1, 2008

KEMA hereby certifies that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Directive 98/79/EC of October 27, 1998 concerning in vitro diagnostic medical devices, including all subsequent amendments, and that the design of the product(s) falling within the product category mentioned above, conforms to the relevant provisions of the Council Directive 98/79/EC of October 27, 1998, in accordance with Annex III, section 6 of this Directive. The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: **August 1, 2011**
Issued for the first time: May 2, 2005 (TNO)
Renewed: August 1, 2008


drs. G.J. Zoetbrood
Managing Director


dr. ir. G.W. Bos
Certification Manager

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ADDENDUM

Belonging to certificate: 2112853DE01

EC DESIGN-EXAMINATION IN VITRO DIAGNOSTIC MEDICAL DEVICES

Solid Phase Immunoassay for the Detection of Human Chorionic Gonadotrophin (hCG) in Urine

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Pompano Beach, FL 33069
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This certificate covers the following product(s):

One Step Pregnancy Test Strip
One Step Pregnancy Test Slide
Pregnancy Test Midstream Wand
One Step Dipstream Pregnancy Test

Initial date: August 1, 2008

Revision date: -

drs. G.J. Zoetbrood
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