

CERTIFICATE

Number: 2109126DE01



EC DESIGN-EXAMINATION IN VITRO DIAGNOSTIC MEDICAL DEVICES

Issued to:

Diagnostic Innovations Limited

5/6/7 Spectrum House
Llys Edmund Prys
St. Asaph Business Park
LL17 0JA ST. ASAPH
GREAT BRITAIN

For the product(s) / product category:

Imutest Allergy Check

KEMA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2109126CN, initially dated February 6, 2008
Addendum, initially dated February 6, 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.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: February 1, 2011

Issued for the first time: February 6, 2008

Revised: January 27, 2009

drs. G.J. Zoetbrood
Managing Director

dr. ir. G.W. Bos
Certification

Manager

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KEMA Medical

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Belonging to certificate: 2109126DE01

**EC DESIGN-EXAMINATION
IN VITRO DIAGNOSTIC MEDICAL DEVICES****Imutest Allergy Check**

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This certificate covers the following product(s):

Imutest Hayfever
Imutest House Dust Mite
Imutest Cat
Imutest Milk
Imutest Egg
Imutest Allergy Check (for total IgE)

Initial date: February 6, 2008
Revision date: January 27, 2009



drs. G.J. Zoetbrood
Managing Director



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