

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
St. Asaph LL17 0JA
Great Britain

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

Self Test for Allergy

DEKRA 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 6 February 2008 Addendum, initially dated 6 February 2008

DEKRA 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 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: 1 February 2014
Issued for the first time: 6 February 2008
Reissued: 21 February 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.

ADDENDUM

Belonging to certificate: 2109126DE01

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This certificate covers the following product(s):

Imutest "Self Test for Allergy" products:

- Imutest Allergy Check
- Imutest Cat
- Imutest Dust Mite
- Imutest Egg
- Imutest Hayfever
- Imutest Milk
- Imutest Airborne Screen

"Boots Pharmaceuticals Self Test for Allergy":

- Boots Multi Allergy Test

Initial date: 6 February 2008

Revision date: 21 February 2011

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan.

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