

CERTIFICATE

Number: 2110187CE02



CE MARKING OF CONFORMITY IN VITRO DIAGNOSTIC MEDICAL DEVICES

Issued to:

Health Protection Agency
Centre for Infections
Quality Control Reagents Unit
61 Colindale Avenue
NW9 5HT LONDON
GREAT BRITAIN

For the product category:

Quality Control Reagents

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 2110187CN, initially dated December 17, 2007
Addendum, initially dated December 17, 2007

KEMA hereby declares 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 for the above mentioned product category the Conformity Assessment Procedure Annex V in combination with Annex VII for Annex II list B products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 98/79/EC of October 27, 1998. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: January 1, 2011
Issued for the first time: December 17, 2007

drs. G.J. Zoetbrood
Managing Director

dr. ir. G.W. Bos
Certification Manager

© Integral publication of this certificate is allowed.

KEMA Medical

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