

CERTIFICATE

Number: 2110187TE02



EC TYPE-EXAMINATION 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

Documents, that form the basis of this certificate:

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

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 type of the products 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 V in combination with Annex VII 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: January 1, 2011
Issued for the first time: December 17, 2007

drs. G.J. Zoetbrood
Managing Director

dr. ir. G.W. Bos
Certification Manager

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KEMA Medical

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