CERTIFICATE

Number: 2128940CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Issued to:

Laboratoires MABIO International
96, rue du Pont Rompu
59203 Tourcoing Cedex
France

For the product category:

CLINIcell® Cell Culture Cassettes for storage of cells and tissues for subsequent infusion, administration or introduction into the body

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 2111774CN, initially dated 20 March 2008
Addendum, initially dated 4 October 2010

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning 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 class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. 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: 1 December 2015
Issued for the first time: 4 October 2010
Reissued: 1 December 2012

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

DEKRA Certification B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2128940CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

CLINIcell® Cell Culture Cassettes for storage of cells and tissues for subsequent infusion, administration or introduction into the body

Issued to:

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96, rue du Pont Rompu
59203 Tourcoing Cedex
France

This certificate covers the following product(s):

00113 CLINIcell® 250 (non plasma treated) with an optimal volume of 125 ml
00114 CLINIcell® 250 (plasma treated) with an optimal volume of 125 ml
00109 CLINIcell® 25 (non plasma treated) with an optimal volume of 10 ml
00110 CLINIcell® 25 (plasma treated) with an optimal volume of 10 ml

Initial date: 4 October 2010
Revision date: 15 August 2011

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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