

# CERTIFICATE

Number: 85225CE05



## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Nucletron B.V.**Waardgeld 1  
3905 TH Veenendaal  
The Netherlands

For the product category:

**Biodegradable spacers**

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 85225CN, initially dated May 8, 1998**  
**Addendum, initially dated October 19, 2004**

KEMA 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 II, section 3 for class III 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: July 1, 2010  
Issued for the first time: January 15, 2002  
Reissued: November 26, 2009

KEMA Quality B.V.

drs. G.J. Zoetbrood  
Managing DirectorM. McCann  
Certification Manager

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# ADDENDUM

Belonging to certificate: 85225CE05

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### Biodegradable spacers

Issued to:

**Nucletron B.V.**  
Waardgelder 1  
3905 TH Veenendaal  
The Netherlands

This certificate covers the following product(s):

- SelectSpacer, model number 130.010

Initial date: October 19, 2004

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
Certification Manager

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