



# CERTIFICATE

Number: 2119117CE01



## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Axiomed Spine Corporation**5350 Transportation Bvd., Suite 18  
Garfield Heights, OH 44125  
USA

For the product category:

**Implants for Treatment of Spinal Degenerative Disease and Associated Surgical Accessories**

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 2119117CN, initially dated May 7, 2009**  
**Addendum, initially dated May 7, 2009**

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 IIb 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: **May 1, 2011**

Issued for the first time: May 7, 2009

drs. G.J. Zoetbrood  
Managing Directordr. ir. G.W. Bos  
Certification Manager

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# ADDENDUM

Belonging to certificate: **2119117CE01**

## CE MARKING OF CONFORMITY MEDICAL DEVICES

**Implants for Treatment of Spinal Degenerative Disease and Associated Surgical Accessories**

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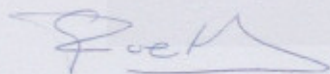
USA

This certificate covers the following product(s):

Freedom Lumbar Disc™ (FLD) (Class IIb)

Initial date: May 7, 2009

Revision date: -



drs. G.J. Zoetbrood  
Managing Director



dr. ir. G.W. Bos  
Certification Manager

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**KEMA Medical**

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