



CERTIFICATE

Number: 2119117CE02



CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Axiomed Spine Corporation5350 Transportation Bvd., Suite 18
Garfield Heights, OH 44125
USA

For the product category:

Surgical Tools and Accessories for the Treatment of Spinal Degenerative Disease

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 V in combination with Annex VII for Class I, measuring 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, 2009drs. G.J. Zoetbrood
Managing Directordr. ir. G.W. Bos
Certification Manager

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ADDENDUM

Belonging to certificate: **2119117CE02**

CE MARKING OF CONFORMITY MEDICAL DEVICES

Surgical Tools and Accessories for the Treatment of Spinal Degenerative Disease

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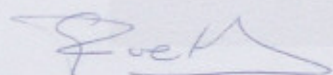
USA

This certificate covers the following product(s):

Disc Trial Sizers (Class I, measuring)

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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