

# CERTIFICATE

Number: 87053CE01



## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**TMJ Implants, Inc.**  
17301 West Coifax Avenue  
Suite 135  
Golden, CO 80401  
USA

For the product category:

**Fossa-Eminence and Condylar Prosthesis Systems**

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 87053CN, initially dated July 29, 1998**  
**Addendum, initially dated December 1, 2001**

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 14 June 1993 concerning medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex V, for Class IIb products in combination with Annex III and Annex VII for class IIa, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of 14 June 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: **October 1, 2010**  
Issued for the first time: July 29, 1998  
Renewed: July 31, 2007



drs. G.J. Zoetbrood  
Managing Director



dr. ir. G.W. Bos  
Certification Manager

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**KEMA Medical**

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# ADDENDUM

Belonging to certificate: 87053CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

### Fossa-Eminence and Condylar Prosthesis Systems

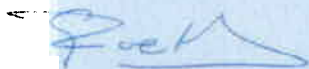
Issued to:

**TMJ Implants, Inc.**  
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Suite 135  
Golden, CO 80401  
USA

This certificate covers the following product(s):

TMJ Fossa-Eminence and Condylar Prosthesis System (Class IIb)  
TMJ Condylar Prosthesis Systems (Class IIb)  
TMJ Condylar Prosthesis Trial Sizing Systems (Class IIa)  
Prosthesis System Accessories (Class IIa)

Initial date: December 1, 2001  
Revision date: July 25, 2006

A handwritten signature in blue ink, appearing to read "Zoetbrood".

drs. G.J. Zoetbrood  
Managing Director

A handwritten signature in blue ink, appearing to read "G.W. Bos".

dr. ir. G.W. Bos  
Certification Manager

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