



# CERTIFICATE OF ASSESSMENT - EC

## DET NORSKE VERITAS

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Social Affairs.

**Certificate N°.: 3843-2007-CE-NOR**

*This is to certify that the Quality System for the product group:*

### **Bone Void Filler Systems**

- defined by manufacturer as Class III devices -

*Manufactured by*

**Central Medical Technologies, Inc.**

3F, 298 Rueiguang Rd., Neihu District, Taipei, Taiwan, R.O.C.

**complies with the applicable requirements of the Directive.**

The quality system for these products has been assessed according to the procedure of conformity assessment described in **Article 11.1.a) and Annex II**. Identification of the products covered by this certificate is given in the Appendix.

#### **Limitations:**

The manufacturer must inform Det Norske Veritas Certification AS of any plan for significant changes to the quality system. Annual Periodical Audits will be held to verify the validity of this Certificate.

*Høvik, 01 June 2007*

for Det Norske Veritas Certification AS

*Marianne Spæren*  
for Marianne Spæren  
Head of section,  
Product Certification

**CE**  
**0434**

*Valid until: 01 June 2012*

*Aud Løken Eiklid*  
Aud Løken Eiklid  
Service responsible Medical Devices

*This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC*



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**CERTIFICATE OF ASSESSMENT - EC      APPENDIX**

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**Appendix to Certificate No.:**    3843-2007-CE-NOR  
**Manufacturer:**                    Central Medical Technologies, Inc.  
**Product group:**                    Bone Void Filler Systems

**This certificate is accompanied with EC design examination certificate no. 3843-2007-CE-NOR**

The Certificate referred to above covers the following devices:

- **Osteo-G Bone Void Filler Pellet**
- **Osteo-G Bone Void Filler Kit**
- **Vessel-X Bone Filling Container System**

**The complete list of medical devices is filed with the Notified Body, ref.: project no. PRJC-05664-2007-PRC-NOR**

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01 June 2007

Aud Løken Eiklid



# EC design-examination certificate Medical Devices



**Design Approval no. 3843-2007-CE-NOR**

<b>Manufacturer name:</b> Central Medical Technologies, Inc.	
<b>Manufacturer address:</b> 3F, 298 Rueiguang Rd., Neihu District, Taipei, Taiwan, R.O.C	
<b>Type of medical device and identification no.:</b>  <b>Bone Void Filler Systems</b> <ul style="list-style-type: none"> <li>Type: Osteo-G Bone Void Filler Pellet</li> <li>Type: Osteo-G Bone Void Filler Kit</li> <li>Type: Vessel-X Bone Filling Container System</li> </ul>	<b>Class of Medical Device:</b>  III
<b>Short description of the medical device:</b>  The <b>Osteo-G Bone Void Filler</b> system consists of pre-measured surgical grade calcium sulfate. These products are provided sterile for single patient use. When mixed according to directions, the Osteo-G Bone Void Filler produces biodegradable, radiopaque moulded pellets that resorb in approximately 60 days when used according to labelling.  The <b>Vessel-X Bone Filling Container System</b> consists of Polyethylene Terephthalate Titanium. The device is to provide bone cement containment with different shapes that intends to reduce the surgical risk far more significantly than any traditional device.	
<b>This is to certify that the <i>medical device</i> fulfils the relevant requirements for Directive 93/42/EEC concerning medical devices.</b>	
<b>Limitations:</b>	
Any changes in the Design shall immediately be reported to Det Norske Veritas Certification AS in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.	

**This certificate is valid until: 2012-06-01**

for DET NORSKE VERITAS CERTIFICATION AS  <i>Marianne Spæren</i> for <i>Marianne Spæren</i> Head of section, Product Certification	Høvik, 01 June 2007  <i>Aud Løken Eiklid</i> Aud Løken Eiklid Service responsible Medical Devices
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