

### CERTIFICATE

Number: 93741CE01

### CE

# CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

BeamMed Ltd.

8 Ha-Lapid Street 49170 PETAH TIKVA ISRAEL

For the product category:

**Ultrasound Diagnostic 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 87757CN, initially dated July 10, 1998 Addendum, initially dated July 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 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 IIa 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: July 10, 1998 Reissued: January 15, 2008

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: 93741CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

**Ultrasound Diagnostic Systems** 

Issued to:

BeamMed Ltd.

8 Ha-Lapid Street 49170 PETAH TIKVA ISRAEL

This certificate covers the following product(s):

Ultrasonic Bone Sonometer Units and Ultrasound Probes (Class IIa)

- Sunlight Omnisense
- Sunlight Omnisense 7000
- Sunlight Omnisense 8000
- Ultrasound Probes: models CM, CS and CR

Ultrasonic Bone Age devices (Class IIa)

Model BonAge

Initial date: July 1, 2001

Revision date: January 15, 2008

drs. G.J. Zoetbrood Managing Director dr. ir. G.W. Bos Certification Manager

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#### **KEMA Medical**

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