

CERTIFICATE

CE MARKING OF CONFORMITY

MEDICAL DEVICES

Number: 93741CE01

Issued to:

Sunlight Medical, Ltd.

5 Tuval Street
P.O. Box 25222
61251 Tel Aviv
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 specified in the Certification Notice and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

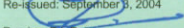
Certification Agreement 2012021, initially dated July 1, 2001
Certification Notice 87757CN, initially dated July 10, 1998
Addendum, initially dated: July 1, 2001

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 14 June 1993 concerning medical devices, and that for the above mentioned product category as specified in the addendum belonging to this certificate, the Conformity Assessment Procedure Annex II, for Class II products, 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: **July 1, 2007**

Issued for the first time: July 10, 1998 (under Annex V/VII)

Re-issued: September 8, 2004


Drs. Ing. Ed. Duim
Managing Director

ADDENDUM

CE MARKING OF CONFORMITY

MEDICAL DEVICES

Belonging to certificate: 93741CE01

Ultrasound Diagnostic Systems

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This certificate covers the following products:

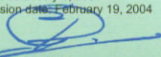
Ultrasonic Bone Sonometer Units and Ultrasound Probes (Class IIa)

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

Ultrasonic Bone Age devices (Class IIa)

- Model BonAge

Initial date: July 1, 2001
Revision date: February 19, 2004



Drs. ing. E.J. Duim
Managing Director

© Integral publication of this certificate is allowed.

CECMDA20 add.1R0