

CERTIFICATE

Number: 2113639CE01



CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Voyant Health Ltd.35 Efal street, 12th floor
Petah-tikva 49511
Israel

For the product category:

Software used for orthopedic preoperative planning

KEMA Quality 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 2113639CN, initially dated March 27, 2008
Addendum, initially dated March 27, 2008

KEMA Quality 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 measurement 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: February 1, 2011
Issued for the first time: March 27, 2008
Revised: January 26, 2010

KEMA Quality B.V.

drs. G.J. Zoetbrood
Managing DirectorM. McCann
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

KEMA MedicalKEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 26 356 2000 F +31 26 352 5800 www.kemaquality.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2113639CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Software used for orthopedic preoperative planning

Issued to:

Voyant Health Ltd.
35 Efal street, 12th floor
Petah-tikva 49511
Israel


This certificate covers the following product(s):

TraumaCad, version 2.y.z

Initial date: March 27, 2008

Revision date: January 26, 2010

KEMA Quality B.V.



drs. G.J. Zoetbrood
Managing Director



M. McCann
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

KEMA Medical

KEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 26 356 2000 F +31 26 352 5800 www.kemaquality.com Company registration 09085396