

CERTIFICATE

Number: 2113639CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Voyant Health Ltd.

35 Efal Street
Petach-Tikva 49511
Israel

For the product category:

Software used for orthopedic preoperative planning

DEKRA 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 27 March 2008
Addendum, initially dated 27 March 2008

DEKRA 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: 1 February 2014
Issued for the first time: 27 March 2008
Revised: 1 February 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 2113639CE01

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CE MARKING OF CONFORMITY MEDICAL DEVICES

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This certificate covers the following product(s):

TraumaCad, version 2.y.z

Initial date: 27 March 2008
Revision date: 7 December 2010

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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