

CERTIFICATE

Number: 2112773CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Fluorinex Active Ltd.

Kochav Yokneam bldg.
Yokneam Industrial Zone
P.O Box 43
Yokneam Ilit 20962
Israel

For the product category:

Dental anti-caries treatment systems based on electrolysis and dental impression tray technology

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 2112773CN, initially dated 18 July 2008
Addendum, initially dated 18 July 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 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: 1 August 2014
Issued for the first time: 18 July 2008
Revised: 1 August 2011
Reissued: 1 August 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: 2112773CE01

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CE MARKING OF CONFORMITY MEDICAL DEVICES

Dental anti-carries treatment systems based on electrolysis and dental impression tray technology

Issued to:

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Israel

This certificate covers the following product(s):

- Fluoritray system (Class IIa)

Initial date: 18 July 2008

DEKRA Certification B.V.

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

drs. G.J. Zoetbrood
Managing Director

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

ing. A.A.M. Laan
Certification Manager

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