

## Urgent Field Safety Notice

**Product:** DentalEye version 3.1  
**To:** Users and distributors of the DentalEye software  
**Action:** Field safety corrective action  
**Date:** 2014-12-09  
**FSN-ID:** #716-20141209

### Safety information

In a decision dated 2014-12-02, the Swedish Medical Products Agency prohibits DentalEye AB from marketing, selling and delivering the non-CE marked software DentalEye.

The Medical Products Agency imposed a market ban on 2011-11-21 for the product DentalEye due to the lack of CE marking.

### Corrective action

All DentalEye systems that have been delivered since 2011-11-21 in violation of the market ban will be recalled and replaced with a CE marked version no later than 2015-12-31, in accordance with the decision of the Medical Products Agency.

If the replacement does not take place, the software will be blocked from accepting new patient information. Thus, no delivered software licenses will be subject for renewal after 2015-12-31.

### Instructions

The purpose of this Field Safety Notice is to allow users and distributors to prepare well in advance of the recall and replacement to a CE marked version.

The process of CE marking the DentalEye software is well under way and is expected to be completed before 2015-12-31. We will contact all affected customers and distributors as soon as the CE marking is completed to plan the software replacement.

The information in this Field Safety Notice must be passed on to all users who may be affected.

Please submit a written reply of this Field Safety Notice via email, fax or mail, as soon as possible. See below for contact information. By replying, you acknowledge receipt of this notice and accept to follow and apply the safety instructions.

**Please submit the reply form no later than 2015-03-02.**

### Contact details

**Manufacturer:**

DentalEye AB  
Kavallerivägen 30  
SE-174 58 Sundbyberg  
SWEDEN

**Telephone:**

+46 (0)8 621 07 00

**Telefax:**

+46 (0)8 621 07 55

**Email:**

[info@dentaleye.com](mailto:info@dentaleye.com)

We confirm that this information has been submitted to the appropriate regulatory agencies.

Our highest priority is to maintain a high level of quality and safety. We regret any inconvenience that this action may cause and we thank you in advance for your assistance. Please contact us if there are any questions.

Yours sincerely,

*Anders Berggren*  
Chief Executive Officer  
DentalEye AB

*Jan Söderlund*  
Quality Manager  
DentalEye AB

## Customer Reply Form

Please fill in this form and return it to DentalEye AB as soon as possible. Thank you!

*I hereby confirm that I have received the Field Safety Notice and that I accept to follow and to apply the safety instructions.*

<b>Signature</b>
<b>Name</b>
<b>Date</b>
<b>Company/practice name</b>
<b>Address</b>
<b>Telephone or email</b>

Please send the form by FAX to +46 (0)8 621 07 55

or via mail to

DentalEye AB  
Kavallerivägen 30  
SE-174 58 Sundbyberg  
SWEDEN

or e-mail to [info@dentaleye.com](mailto:info@dentaleye.com)