

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate Number
41319464

Initial Certification Date
April 8, 2016

Certificate Valid from
April 8, 2016

Certificate Expiry Date
April 7, 2021

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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Ackred. nr 1003
ISO/IEC 17021

Organization:

DentalEye AB

Kavallerivägen 30, SE-174 58 Sundbyberg, Sweden

Product Category:

Dental imaging software intended for image acquisition, storage, manipulation and diagnosis of dental images

For further identification of the products covered, see the MDD product list/product schedule.

April 8, 2016
Signed date

Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41319464
 Issued to: **DentalEye AB**
 Kavallerivägen 30
 SE-174 58 Sundbyberg
 Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Dental imaging software intended for image acquisition, storage, manipulation and diagnosis of dental images					
	DentalEye Pro, Enterprise and Viewer (version 3.x)	Ila	No	-	Apr 8, 2016

Date of Issue: May 23, 2019

Intertek Semko AB
 Notified Body MDD


 Peter Nermander
 Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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