EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

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

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.

Organization:

DentalEye AB

Main Site: 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.

Certificate Number:
41319464-01

Initial Certification Date:
8 April 2016

Certificate Valid from:
8 April 2021

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Mikael Hagelin
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

19 February 2021
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

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.

MDD – Decision Report

Certificate No: 41319464
Date: 19 February 2021
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

DentalEye AB
Attn: Marcus Johansson
Kavallerivägen 30
SE-174 58 Sundbyberg
Sweden

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 13 January 2021 in Sundbyberg by Tuomas Toivonen. The technical file was reviewed 27 October 2020 by Lian Zhang at Intertek's office.
Scope of assessment	Dental imaging software intended for image acquisition, storage, manipulation and diagnosis of dental images; class IIa
Result	3 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	8 April 2021
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Mikael Hagelin
Certification Authority MDD

MDD – Product List

Products included in the Certificate No: 41319464-01
Issued to: **DentalEye AB**
Kavallerivägen 30
SE-174 58 Sundbyberg
Sweden

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

Sign Date: 19 February 2021
Valid Date: 8 April 2021

Intertek Semko AB
Notified Body MDD

Mikael Hagelin
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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