

EC Declaration of Conformity

Manufacturer	DentalEye AB Kavallerivägen 30 SE-174 58 Sundbyberg SWEDEN
Product	DentalEye 3.2 Dental image management software
Classification	Class IIa medical device, according to rule 10 of Annex IX of the MDD
Conformity assessment route	Annex II

We herewith declare that the above-mentioned product meets the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices, as well as the Swedish national regulation LVFS 2003:11. All supporting documentation is retained on the premises of the manufacturer.

Standards applied

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 62304:2006	Medical device software - Software life cycle processes
EN 62366:2008	Medical devices – Application of usability engineering to medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices

Notified body Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, SWEDEN
Notified Body identification number: 0413

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Signature 
Anders Berggren
CEO