iCAD

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EC DECLARATION OF CONFORMITY

CE 0473

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Declares under sole responsibility that the **VeraLook™ CT Colon CAD Product** (Product No: CT-100, CT-101, CT-100-V and CT101-V) to which this declaration relates meets the essential health and safety requirements and is in conformance with the relevant EC directives listed below using the relevant section of the EC standards and other normative documents.

EU Medical Device Directive 93/42/EEC

Council Directive concerning medical devices complies with all the requirements of the Essential Requirement of all the provisions of the Medical Device Directive (MDD).

MDD Class: Class IIa. The classification is based on the requirements of Rule 2.3 of Annex IX, of the Medical Device Directive.

Quality Systems Certification: ISO 13485:2003 as indicated on certificate number 9213, granted by Intertek.

The CE Mark is applied under the guidelines of Annexes II of the Medical Device Directive 93/42/EEC. Product Quality Assurance EC Certificate No. CE 877 B CE.

CE Mark: Article 17 of the Medical Device Directive 93/42/EEC.

Date of the CE Marking: 01/28/2011

iCAD, Inc's Authorized Representative in the European Community (as defined in Article 14 of the medical Device Directive: 93/42/EEC):

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John A. DeLucia
Vice President of Regulatory Affairs and Quality Assurance

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