



EC DECLARATION OF CONFORMITY



**iCAD, Inc. (Manufacturer)**  
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Declares under sole responsibility that the product **SecondLook® Premier (Product No: D70084 and D70085)** to which this declaration relates meets the essential health and safety requirements and is in conformance with the relevant EC directive listed below using the relevant section of the EC standards and other normative documents:

Medical Device Directive 93/42/EEC

**MDD Class:** Class I. The classification is based on the requirements of Rule 12 of Annex IX, of the Medical Device Directive.

**Quality Systems Certification:** ISO 13485:2003 as indicated on certificate number 672447, granted by BSI.

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

**GMDN Code:** 58473

**Date of the CE Marking and Production Date:** January 23, 2018.

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

MDSS GmbH  
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30175 Hannover, Germany

Management Representative, John A. DeLucia  
Vice President of Regulatory Affairs, Clinical Affairs and Quality Assurance

DTB085 Rev. B