



EC DECLARATION OF CONFORMITY



iCAD, Inc. (Manufacturer)  
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Declares under sole responsibility that the product **SecondLook® Digital 7.2 (Product No:)** (D70074, D70075, D70076, D70077, D70079, D70088, D70089, D70090, D70091, D70092, D70093, D70094, D70096, D70097, D70100, D70103, D70104, D70107, D70135, D70138, D70144, and D70159) 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 13485:2016 as indicated on certificate number 703029, 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, Heather Reed  
Vice President, Quality Assurance & Regulatory Affairs

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