EC DECLARATION OF CONFORMITY

CE 2797

iCAD, Inc. (Manufacturer)
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Declares under sole responsibility that the ProFound AI **(PowerLook Tomo Detection Software) Product No's: DSC014-01-ROW, DSC014-02-ROW, D70129, and D70131** 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 10 of Annex IX, of the Medical Device Directive.

Quality Systems Certification: ISO 13485:2016 as indicated on certificate number 703029, granted by BSI.

The CE Mark is applied under the guidelines of Annex II excluding section 4 of the Medical Device Directive 93/42/EEC. Product Quality Assurance EC Certificate No. 649468.

CE Mark: Article 17 of the Medical Device Directive 93/42/EEC.
GMDN Code: 58473
Date of the CE Marking and Production Date: February 27, 2018.

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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Heather Reed
VP of RA/QA

Date: October 30, 2019

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