EC DECLARATION OF CONFORMITY CE 0086

iCAD, Inc. (Manufacturer)
98 Spit Brook Road, Suite 100
Nashua, New Hampshire 03062
Phone: +1 937-431-1464 Fax: +1-603-880-3843

Declares under sole responsibility that the **PowerLook Tomo Detection Software Product No's: DSC014-01-ROW and DSC014-02-ROW, D70149, D70150, D70151, D70152, D70153, D70154, D70155 and D70156,** 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 13485:2003 as indicated on certificate number 672447, granted by BSI.

The CE Mark is applied under the guidelines of Annex II 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):

Medical Device Safety Service (MDSS)
Schiffgraben 41, 30175 Hannover, Germany
Tel: + 49 – 511 – 6262 8630 Fax: + 49 – 511 – 6262 8633
Email: info@mdss.com ---- Internet: www.mdss.com

iCAD, Inc's Notified Body in the European Community:

BSI
Kitemark Court
Davy Avenue
Knowlhill, Milton Keyes MK5 8PP
Tel: +44 345 080 9000

John A DeLucia Date: February 27, 2018
Vice President of Regulatory Affairs, Clinical Affairs and Quality Assurance

DTB137 Rev. D