EC DECLARATION OF CONFORMITY CE 2797

iCAD, Inc. (Manufacturer)
98 Spit Brook Road, Suite 100
Nashua, New Hampshire 03062
+1 603-882-5200
Fax: - 1-603-880-3843

Declares under sole responsibility that the **VeraLook® CT Colon CAD Product** (Product No: CT-102, CT102-V, D70070 and D70071) 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 13485:2016 as indicated on certificate number FM 703029, granted by BSI.

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. CE649468

CE Mark: Article 17 of the Medical Device Directive 93/42/EEC.
Date of the CE Marking: January 23, 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 – 62 62 86 30 Fax: + 49 – 511 – 62 62 86 33
Email: info@mdssar.com ---- Internet: www.mdssar.com

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

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Country: Netherlands
Tel: +31 (0)20 246 07 80

Heather Reed
VP of RA/QA

10/30/2019
Date

DTB078 Rev. G

APPROVED 10/30/2019