

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Heart Imaging Technologies, LLC

(FIN F003464)

Main Site: 6th floor, 305 Church at N Hills St.,  
Raleigh, North Carolina, 27609, United States

has been registered by Intertek, an MDSAP recognized auditing organization,  
as conforming to the requirements of:

### ISO 13485:2016

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

**Brazil:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012;  
RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

### The management system is applicable to:

*Design, manufacture, installation and servicing of medical image workstation software for analysis of images in DICOM format for use in diagnosis of heart physiology and function, and generating and reviewing reports.*

**Certificate Number:**

0086717-02

**Initial Certification Date:**

2019-01-30

**Date of Certification Decision:**

2022-09-13

**Certification Effective Date:**

2022-09-14

**Certification Expiry Date:**

2025-01-29



intertek

**Calin Moldovean**

President, Business Assurance

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