

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Heart Imaging Technologies, LLC

(FIN F003464)

Main Site: 5003 Southpark Drive, Suite #140

Durham, NC 27713-9414 United States

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

ISO 13485:2016

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:

0086717-01

Initial Certification Date:

2019-01-30

Date of Certification Decision:

2022-03-07

Certification Effective Date:

2022-03-07

Certification Expiry Date:

2025-01-29



intertek

Calin Moldovean

President, Business Assurance

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