

# Certificate US19/819943340

The quality management system of

## INVIA, LLC

3025 Boardwalk Drive, Suite 200, Ann Arbor, MI, 48108, United States Of America  
Facility number: F003359

has been assessed and certified as meeting the requirements of

### **MDSAP (ISO 13485:2016)**

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada: Medical Device Regulations SOR/98-282, Part 1 - General

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, development, manufacturing, distribution, and installation of medical imaging software/systems for the analysis of nuclear, PET, and CT images.

This certificate is valid from Effective date 2025-02-23 until Expiry date 2028-02-23 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2019-08-27



Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at [www.SGS.com](http://www.SGS.com).



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