Certificate Number US19/819943340

The quality management system of

INVIA, LLC

3025 Boardwalk Drive, Suite 200, Ann Arbor, MI, 48108, United States

Facility identification number: F003359

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Canada:

Medical Devices Regulations - Part 1 SOR 98/282

<u>United States:</u>

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 - Subparts A to D

For the following activities and devices

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

This certificate is valid from Effective Date: 2022-02-24 until Expiry Date: 2025-02-23 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 2025-02-07 Issue 2. Certified since 2019-08-27

Authorised by LHenderson Business Manager

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Page 1 of 1





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