Certificate US22/819944903

The quality management system of

Segami Corporation

8310 Guilford Road, Suite A, Columbia, MD, 21046, United States Of America
Facility number: F001070

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Device Regulations SOR/98-282, Part 1
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, manufacture, distribution and servicing of medical molecular imaging software for the acquisition, processing, review and archiving of radiological images.

This certificate is valid from Effective date 2024-05-05 until Expiry date 2027-03-31 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2018-12-26

L. Henderson

Authorised by
Lynn Henderson
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.