

EU Quality Management System Certificate US26/00000176

The management system of

Segami Corporation



8310 Guilford Road, Suite A, Columbia, MD 21046, United States of America
SRN Number: US-MF-000002014

has been assessed and certified as meeting the requirements of
MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 21 April 2026 until 21 April 2031 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 21 October 2030

Issue 1. Certified since 21 April 2026



Authorised by

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Head of Certification and
Compliance

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EU Quality Management System Certificate US26/00000176,
continued

Segami Corporation

SGS

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa Device

Codes: MDA 0315, MDS 1009, MDS 1010

Medical molecular imaging software system for the acquisition,
processing, and review of radiological images.

Basic UDI-DI: 00857198006013

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - WW/MD5/620858 - S2A 1.3 +TFR 1.2

Authorized representative name and address (if relevant): MedEnvoy Global B.V. ; Prinses
Margrietplantsoen 33, Suite 123, 2595 AM, The Hague, The Netherlands

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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