



CERTIFICATE OF REGISTRATION

This is to certify that

Actim Oy

Klovinpellontie 3, Fi - 02180 Espoo, Finland

D-U-N-S: 368646046

Refer to Attachment to Certificate of Registration dated January 6, 2020 for additional certified sites operates a

Quality Management System

which complies with the requirements of

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

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

Brazil:

- RDC ANVISA n. 16/2013 - Good Manufacturing Practices
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009 - Vigilance

Canada:

- Medical Device Regulations SOR/98-282, Part 1

Japan:

- MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68
- Japan PMD Act (as applicable)

United States:

- 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 scope of certification

The design and development, manufacture, distribution and service, of in-vitro diagnostic analyzers, in-vitro diagnostic test kits, controls and reagents used in diagnosis and screening of pregnancy, disease status, and endocrine disorders, including near patient in-vitro diagnostic devices.

Certificate No.: CERT-0104388

File No.: 025778

Issue Date: 2020-01-08

Original Certification Date: 2018-12-17

Certification Effective Date: 2018-12-17

Certificate Expiry Date: 2021-12-16

Heather Mahon
Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an authorized MDSAP auditing organization.



Registered by:
QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.
To verify that this certificate is current, please refer to the SAI Global On-Line Certification Register:
https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_register/



ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0104388 issued on January 6, 2020

File No.

Effective Date

025778

Actim Oy

Klovinpellontie 3, Fi - 02180 Espoo, Finland

D-U-N-S: 368646046

Quality Management, Sales, Design, Receiving, Production, HR, and Management.

2018-12-17

025779

Actim Oy

Noljakantie 13, Fi - 80130 Joensuu, Finland

D-U-N-S: 368646046

Production, Storage and Shipping.

2018-12-17