



# CERTIFICATE OF REGISTRATION

This is to certify that

## Oy Medix Biochemica Ab

Klovinpellontie 3, Fi - 02180 Espoo, Finland  
D-U-N-S: 368676966

Refer to Attachment to Certificate of Registration dated December 17, 2018 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 and 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

Original Certification Date: 2018-12-17

File No.: 025778

Certification Effective Date: 2018-12-17

Issue Date: 2018-12-17

Certification Expiry Date: 2021-12-16

Kevin Goodwin

General Manager Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP  
authorized 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: [www.qmi-saiglobal.com/qmi\\_companies/](http://www.qmi-saiglobal.com/qmi_companies/)



# ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT- 0104388 issued on 2018-12-17

File No.		Effective Date
025778	<b>Oy Medix Biochemica Ab</b> Klovinpellontie 3, Fi - 02180 Espoo, Finland D-U-N-S: 368676966 Quality Management, Sales, Design, Receiving, Production, HR, and Management.	2018-12-17
025779	<b>Oy Medix Biochemica Ab Joensuu Site</b> Noljakantie 13, Fi - 80130 Joensuu, Finland D-U-N-S: 368676966 Production, Storage and Shipping.	2018-12-17