



# CERTIFICATE

No. QS6 092656 0005 Rev. 02

**Certificate Holder:** **ALIFAX S.r.l.**  
Via Merano 30  
33045 Nimis (UD)  
ITALY

**Certification Mark:**



**Scope of Certificate:** See Page 2 for Overall Scope Statement.

**Standard(s):** ISO 13485:2016

**Regulatory Authority(ies):** Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_092656\\_0005\\_Rev\\_02](http://www.tuvsud.com/ps-cert?q=cert:QS6_092656_0005_Rev_02)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** F002813  
**Report No.:** ITA200220014445  
**Effective Date:** 2026-04-21  
**Expiry Date:** 2026-09-10

( Renee Walker )  
Director, US Certification Body, MHS



# CERTIFICATE

No. QS6 092656 0005 Rev. 02

## Regulatory Requirements: Audit/Certification Criteria

### Australia

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

### Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices  
- RDC ANVISA n. 551/2021  
- RDC ANVISA n. 67/2009 - Vigilance

### Canada

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

### Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)  
- Japan PMD Act (as applicable)

### United States

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

## Overall Scope Statement:

**Design, Production and Service of In-Vitro Diagnostic Medical Devices (Analyzers, Software and their associated Reagents and / or Controls) used in Hematological, Immunological and Microbiological Professional Fields for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test**

Page 2 of 3

Date of Issue: 2026-04-23

( Renee Walker )  
Director, US Certification Body, MHS



# CERTIFICATE

No. QS6 092656 0005 Rev. 02

**Facility(ies):****ALIFAX S.r.l.**

Via Merano 30, 33045 Nimis (UD), ITALY

**ALIFAX S.r.l.**

Via Petrarca 2/1, 35020 Polverara (PD), ITALY

**Facility Scopes:****ALIFAX S.r.l.**

Via Merano 30, 33045 Nimis (UD), ITALY

Design, Production and Service of In-Vitro Diagnostic Medical Devices (Analyzers, Software and their associated Reagents and / or Controls) used in Hematological, Immunological and Microbiological Professional Fields for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test

REPs Facility ID: F002813

**ALIFAX S.r.l.**

Via F. Petrarca 2/1, 35020 Polverara (PD), ITALY

Design, Production and Service of In-Vitro Diagnostic Medical Devices (Analyzers, Software and their associated Reagents and / or Controls) used in Hematological, Immunological and Microbiological Professional Fields for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test

REPs Facility ID: F002918

( Renee Walker )  
Director, US Certification Body, MHS