ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 092656 0005 Rev. 01

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. 01
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002813**
Report No.: **ITA2108685**
Effective Date: **2023-09-11**
Expiry Date: **2026-09-10**

Date of Issue: 2023-09-15

(Renee Walker)
Director, US Certification Body, MHS

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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 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

Date of Issue: 2023-09-15

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C E R T I F I C A T E

No. QS6 092656 0005 Rev. 01

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 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 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

Date of Issue: 2023-09-15

(Renee Walker)
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