



Certificate

No. Q5 031936 0004 Rev. 03

Holder of Certificate: **ALIFAX S.r.l.**
Via Petrarca 2/1
35020 Polverara (PD)
ITALY

Certification Mark:



Scope of Certificate: Design and Development, Production, Distribution and Servicing and Installation of non-sterile In-Vitro Diagnostic Medical Devices (Analysers, Software and their associated Reagents and Controls) used in Haematological, Immunological, and Microbiological Professional Fields for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anaemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test. The provision of Distribution and Servicing Services of non-sterile In-Vitro Diagnostic Medical Devices (Analysers and their associated Reagents and Controls) used in Allergology, Coagulation and Urine Clinical Chemistry for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anaemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 031936 0004 Rev. 03

Report No.: ITA2108685

Valid from: 2024-02-12
Valid until: 2027-02-11

Date, 2024-02-07



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 031936 0004 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **ALIFAX S.r.l.**
Via Petrarca 2/1, 35020 Polverara (PD), ITALY

Management and Distribution of non-sterile In-Vitro Diagnostic Medical Devices (Analysers, Software and their associated Reagents and Controls) used in Haematological, Immunological, and Microbiological Professional Fields for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anaemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test. The provision of distribution services of non-sterile In-Vitro Diagnostic Medical Devices (Analysers and their associated Reagents and Controls) used in Allergology, Coagulation and Urine Clinical Chemistry for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anaemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test.

ALIFAX S.r.l.
Via Merano 30, 33045 Nimis (UD), ITALY

Management, Design and Development, Production, Distribution and Service and Installation of non-sterile In-Vitro Diagnostic Medical Devices (Analysers, Software and their associated Reagents and Controls) used in Haematological, Immunological, and Microbiological Professional Fields for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anaemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test.

ALIFAX S.r.l.
Viale Europa 2/A, 35020 Ponte San Nicolo' (PD), ITALY

The provision of distribution and servicing and installation services of non-sterile In-Vitro Diagnostic Medical Devices (Analysers) used in Allergology, Coagulation, Urine Clinical Chemistry and in Haematological, Immunological and Microbiological Professional Fields for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anaemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test.

Certificate

No. Q5 031936 0004 Rev. 03

ALIFAX Research & Development S.r.l.

SS 14 Km 163,5, c/o Area Science Park, 34149 Località Basovizza (TS), ITALY

Design and Development and Component Manufacturing of non-sterile InVitro Diagnostic Medical Devices (Reagents and Controls) used in Microbiological Professional Fields for the Diagnosis of Infectious Status.

ALIFAX S.r.l.

Via Nikola Tesla 18, 35020 Brugine, ITALY

The provision of Distribution Services of non-sterile In-Vitro Diagnostic Medical Devices (Reagents and Controls) used in Allergology, Coagulation and Urine Clinical Chemistry for the Diagnosis of Rheumatological, Infectious and Autoimmune Disease and Inflammatory and Anaemia Status, for the Diabetic Patient Monitoring and for the Cultures of Human Biological Liquids together with the Antimicrobial Susceptibility Test.

\