



Certificate

No. Q5 031936 0004 Rev. 02

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 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. Provision of Distribution and Maintenance Servicing of Medical Devices for Sample Collection and Transport of biological and/or perishable material and of 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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_031936_0004_Rev_02)

Report No.: ITA 15673911S

Valid from: 2022-04-05
Valid until: 2024-02-11

Date, 2022-04-05

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Executive Management, Resource Management, Regulatory Affairs Management and Distribution of 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. Provision of Distribution of Medical Devices for Sample Collection and Transport of biological and/or perishable material and of 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

Design and Development, Production, Distribution and Service of 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.

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Facility(ies):

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

Provision of Distribution and Maintenance Serving of Medical Devices for Sample Collection and Transport of biological and / or perishable material and of In-Vitro Diagnostic Medical Devices (Analysers and their associated Reagents and Controls) 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.

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 In-Vitro Diagnostic Medical Devices (Reagents and Controls) used in Microbiological Professional Fields for the Diagnosis of Infectious Status.