Digitally signed by Iurchevici Valeriu
Date: 2022.12.22 15:35:33 EET
Reason: MoldSign Signature
Location: Moldova

www.dialab.at

AUTHORIZATION LETTER

Wr. Neudorf, 10.01.2022

TO WHOM IT MAY CONCERN

We, **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.,** headquarter in Austria, IZ-NÖ Süd, Hondastrasse Obj. M55, A-2351 Wr. Neudorf hereby declares that the below mentioned company is our official **representative** and is authorized to register, sell and distributor our products in the territory of Moldavia:

ECHIPAMED PLUS SRL
Valea Trandafirilor str.; 24B, of.80,
MD-2001 Chisinau, Moldova

This certificate remains in force from 01.02.2022 until 31.01.2023 or is terminated during that period on the expiry of not less than 30 days' notice in writing given by either party to the other.

Signed for and on behalf of
DIALAB GmbH

Murat ESTELIK
Managing Director

REPUBLICA MOLDOVA mun. CHIȘINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 WR. NEUDORF
AUSTRIA
Phone: +43(0)2236 660910-0
Fax: +43(0)2236 660910-30
Mail: office@dialab.at
www.dialab.at
Managing Director/Geschäftsführer
Murat Eslelik, Dipl. Ing. Marlene Ramsey
FN 108 078p | Landesgericht Wr. Neustadt
UID/VAT: ATU 150 136 06 | DVR: 0130885
Raiffeisen Regionalbank Meedling
BIC / SWIFT: RLNWATWWGTB
IBAN €: AT97 3225 0000 0070 6739
IBAN USD: AT52 3225 0301 0070 6739

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 026709 0009 Rev. 01

Holder of Certificate: **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

Scope of Certificate: **Design, development, production and distribution of in-vitro diagnostic reagents and testkits in the areas of immunological detection of infectious diseases, immunochemistry/immunology/clinical chemistry biomarkers (analytes: enzymes, substrates, electrolytes reagents; controls/standards/calibrators), urinalysis, haematology, haemostasis and immunohaematology (blood grouping).
Distribution of in-vitro diagnostic instruments including accessories for immunology, clinical chemistry, haematology, haemostasis and urinalysis.**

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 026709 0009 Rev. 01

Report No.: 713237224

Valid from: 2022-03-29
Valid until: 2025-03-28

«ECHIP-AMED-PLUS» IDNO 1003600007677

Date, 2022-03-17

Christoph Dicks
Head of Certification/Notified Body

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 026709 0009 Rev. 01

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): DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

See Scope of Certificate

Parameters: ./.

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Benannt durch/Designated by
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www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0008 Rev. 02

Manufacturer:

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Product:

Reagents and reagent products for blood typing AB0-system

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. 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:V7 026709 0008 Rev. 02

Report No.: 713255766_2_SCN

Valid from: 2022-05-04
Valid until: 2025-05-26

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0008 Rev. 02

Model(s):

Anti-A, monoclonal
Anti-B, monoclonal
Anti-AB, monoclonal

Facility(ies):

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

Parameters:

Model Name:	Model No:
Anti-A, monoclonal	B05405
Anti-B, monoclonal	B05406
Anti-AB, monoclonal	B05407

MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RASPUNDERE LIMITATA «ECHIPAMED-PLUS» IDNO 1003600077677 REPUBLICA

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0007 Rev. 02

Manufacturer:

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Product:

Reagents and reagent products for blood typing
Rhesus (C,c,D,E,e)

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. 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:V7 026709 0007 Rev. 02

Report No.: 713255766_2_SCN

Valid from: 2022-05-04
Valid until: 2025-05-26

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0007 Rev. 02

Model(s):

Anti-D (IgM/IgG), monoclonal
Anti-C, monoclonal
Anti-c, monoclonal
Anti-E, monoclonal
Anti-e, monoclonal

Facility(ies):

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

Parameters:

Model Name:	Model No:
Anti-D (IgM/IgG), monoclonal	B05408
Anti-C, monoclonal	B06411
Anti-c, monoclonal	B06413
Anti-E, monoclonal	B06412
Anti-e, monoclonal	B06414

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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Manufacturer:

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Product Category(ies): **Products according to Directive 98/79/EC Annex II**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1 026709 0004 Rev. 02

Report no.: 713205839

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-04-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Model(s): **The products detailed below are covered under the scope of this certificate**

Facility(ies): DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf,
AUSTRIA

Products according to Annex II List A Devices:

Product	REF
Anti-A, monoclonal	B05405
Anti-B, monoclonal	B05406
Anti-AB, monoclonal	B05407
Anti-D (IgM/IgG), monoclonal	B05408
Anti-C, monoclonal	B06411
Anti-E, monoclonal	B06412
Anti-c, monoclonal	B06413
Anti-e, monoclonal	B06414
Anti-D Negative Control	B09936
DIAQUICK HIV Plus	H18100
DIAQUICK HIV Plus WB	H18101
DIAQUICK HCV Plus	H18200
DIAQUICK HCV Plus WB	H18201

MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TECHIPAMED-PLUS" IDNO 1003600077677 REPUBLICA

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www.zlg.de
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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Products according to Annex II List B Devices:

Product	REF
Anti-HG, polyspecific/monoclonal	B05181
Rubella IgG	V00045
Rubella IgM	V05061
DIAQUICK Rubella IgM Cassette	J15020
Toxoplasma IgG	V00064
Toxoplasma IgM	V05079
DIAQUICK Toxoplasma IgM Cassette	J15011
CMV IgG	V00004
CMV IgM	V00012
DIAQUICK CMV IgM Cassette	J15030
DIAQUICK Chlamydia Cassette	Z98226CE
PSA	Z00338
DIAQUICK PSA Cassette	Z08010
DiaCheck® Pro Blood Glucose Monitoring System	P13110
DiaCheck® Pro Blood Glucose Test Strips	P13125
DiaCheck® Pro Glucose Control Solution	P13134

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EC DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

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Dialab Produktion und Vertrieb von
chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf

REF	Product Name / Produktname	Content / Inhalt
B05178	LISS Solution	1x 10 mL

We declare, on our own responsibility, that our above-mentioned product classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:
Devices other than those covered by Annex II

meets the applicable provisions of the EU Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on the Conformity Assessment Procedure according to Annex III of the aforesaid Directive.

This Declaration is valid until 2025-03-28.

Hiermit erklären wir, auf eigene Verantwortung, dass unser oben genanntes Produkt, gemäß der Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert als:
Andere als die in Anhang II genannten Produkte

die anwendbaren Vorschriften der EU-Richtlinie 98/79/EG über in-Vitro-Diagnostika und des Österreichischen Medizinproduktegesetzes erfüllt.

Diese Erklärung basiert auf dem Konformitätsbewertungsverfahren nach Anhang III der oben angeführten Richtlinie.

Diese Erklärung ist bis zum 2025-03-28 gültig.

DIALAB
Produktion und Vertrieb von chemisch - technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A - 2351 Wr. Neudorf, IZ-NÖ Süd, Hondastr. Obj.M55
Phone: +43 (0) 2236 660910 - 0 Fax: +43 (0) 2236 660910 - 30
E-Mail: office@dialab.at Website: www.dialab.at

Wiener Neudorf, 2022-03-29

Heidi Kroiß
Qualitätsmanagementbeauftragte
Quality Management Representative

EC DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

www.dialab.at

Dialab Produktion und Vertrieb von
chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf

REF	Product Name / Produktname	Content / Inhalt
Z08070CE	DIAQUICK Microalbumin Dipstick	50 Tests - 50 tests individually packed

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We declare, on our own responsibility, that our above-mentioned product classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:
Devices other than those covered by Annex II

meets the applicable provisions of the EU Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

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Andere als die in Anhang II genannten Produkte

die anwendbaren Vorschriften der EU-Richtlinie 98/79/EG über in-Vitro-Diagnostika und des Österreichischen Medizinproduktegesetzes erfüllt.

Diese Erklärung basiert auf dem Konformitätsbewertungsverfahren nach Anhang III der oben angeführten Richtlinie.

Diese Erklärung ist bis zum 2025-03-28 gültig.

DIALAB
Produktion und Vertrieb von chemisch - technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
A - 2351 Wr. Neudorf, IZ-NOE Süd, Hondastr. Obj.M55
Phone: ++43 (0) 2236 660910 - 0 Fax ++43 (0) 2236 660910 - 30
E-Mail: office@dialab.at Website: www.dialab.at

Wiener Neudorf, 2022-03-29

Heidi Kroiß
Qualitätsmanagementbeauftragte
Quality Management Representative